UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number: 001-39980

Sensei Biotherapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1863385**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1405 Research Blvd, Suite 125	
Rockville, MD	**20850**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (240) 243-8000

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, $0.0001 par value per share	SNSE	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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

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

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

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

There was no aggregate market value of shares of common stock held by non-affiliates of the registrant as of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, because the registrant's common stock was not trading on any exchange on that date.

The number of shares of Registrant's Common Stock outstanding as of March 25, 2021 was 30,588,495.

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PART I

Item 1. Business.

Overview

We are a clinical-stage immunotherapy company engaged in the discovery and development of next-generation therapies with an initial focus on treatments for cancer. Our proprietary ImmunoPhage platform is a powerful, self-adjuvanted and highly differentiated immunotherapy approach that is designed to utilize bacteriophage to induce a robust, focused and coordinated innate and adaptive immune response. We are engineering our ImmunoPhage product candidates to directly target antigen presenting cells, or APCs, and modulate the tumor microenvironment, or TME, through the targeted use of nanobodies which further enhances therapeutic activity. We believe our ImmunoPhage platform has the potential to deliver personalized, off-the-shelf product candidates tailored to a patient's specific tumor. The versatility of our ImmunoPhage platform allows us to design product candidates in a modular fashion, based on a cocktail of common and patient-specific antigens built from our proprietary library of ImmunoPhages, which we refer to as Phortress. We are currently conducting an ongoing 30-patient Phase 1/2 clinical trial of our lead product candidate, SNS-301, in combination with the PD-1 inhibitor pembrolizumab, as a potential treatment for squamous cell carcinoma of the head and neck, or SCCHN. As of March 9, 2021, we have enrolled 17 patients in the trial. As of December 10, 2020, we have evaluated ten patients for efficacy and ten for safety. We have observed disease control in seven of the patients evaluable for efficacy, including one patient with a partial response, or PR, and two patients who have achieved longstanding stable disease, or SD, for greater than 36 weeks following treatment. Treatment with SNS-301 has generally been well tolerated. We anticipate reporting a large additional subset of data from this trial by the end of 2021. If the results of this trial are positive, subject to feedback from the U.S. Food and Drug Administration, or FDA, we intend to initiate a randomized, registration-enabling trial for SNS-301. We are leveraging the insights from our experience with SNS-301 to expand our development pipeline to include SNS-401 for the treatment of Merkel cell carcinoma, or MCC, as well as a human monoclonal antibody, or mAb, program targeting the novel immune checkpoint VISTA, or V-set immunoglobulin domain suppressor of T cell activation.

Monoclonal antibodies targeting the programmed cell death protein 1, or PD-1, and its related ligand, or PD-L1, have emerged as one of the most promising classes of therapeutics for the treatment of cancer. However, in a majority of patients they generally fail to produce meaningful results. Drugs utilizing PD-1 blockade have been approved by the FDA to treat at least 20 different types of cancer and, in 2019, generated sales of approximately $19.4 billion worldwide. By 2024, the total global market for drugs utilizing PD-1 blockade is estimated to exceed $36 billion. Two of the most common reasons for non-response to PD-1 blockade treatment include a lack of tumor infiltrating lymphocytes, or TILs, or the presence of alternate immunosuppressive mechanisms such as VISTA. To address these mechanisms of non-response to PD-1 blockade, there has been considerable focus on the development of therapies that induce the body's immune system to mount a response towards tumor antigen targets. Our ImmunoPhage platform is designed to address the challenges of converting PD-1 blockade non-responsive tumors into responsive ones by triggering the generation of tumor antigen-specific T cells and circumventing immunosuppressive pathways.

Pioneering work with bacteriophage led to our discovery of their utility as a powerful, self-adjuvanted immunotherapy platform. The foundation of ImmunoPhage is the bacteriophage lambda, or lambda phage, which we selected for its native immunostimulatory capabilities, large and tractable genome, and tolerability profile. The highly immunogenic nature of bacteriophage promotes a balanced, coordinated and robust response by both the innate and the cellular and humoral components of the adaptive immune system. We believe that the unique features of bacteriophage, including the ability to generate both T cell responses and B cell mediated antibody responses, give it the potential to be used in the development of differentiated treatments for cancer. The modularity of the ImmunoPhage platform allows for personalized, dynamic substitution of particular phage components to optimize patient therapy. Our creation of a phage cocktail expressing multivalent antigens along with the integration of nanobody technology is designed to enhance the utility, precision and therapeutic activity of our product candidates. This allows for an adaptive clinical trial design, which we have discussed with the FDA. To date, we have constructed over 25 unique ImmunoPhage configurations in-house in accordance with current good manufacturing practices, or cGMP, and we are continuing to expand our Phortress library of ImmunoPhages.

SNS-301 is an ImmunoPhage product candidate that we are developing as a treatment for locally advanced unresectable or metastatic SCCHN. Head and neck cancer is the sixth most common malignancy worldwide, accounting for approximately 6% of all cancer cases, and is responsible for an estimated 1% to 2% of all cancer deaths. An estimated 650,000 cases of head and neck cancer are diagnosed annually worldwide, including approximately 50,000 cases in the United States. Human papilloma virus, or HPV, infection accounts for an estimated 70% of SCCHN cases in the United States. The current standard of care in our target patient population is PD-1 inhibition as a single agent or in combination with chemotherapy. Despite improvements in diagnoses and disease management, long-term survival rates for patients with SCCHN have not increased significantly over the past 30 years and are among the lowest for major cancers.

We selected SCCHN as our first indication based on a high unmet patient need, robust scientific rationale, a clearly defined regulatory path and accessibility of these tumors for biopsy. SNS-301 has been engineered to produce a targeted immune response against the tumor associated antigen, or TAA, aspartate β-hydroxylase or ASPH. ASPH is found to be overexpressed in 70% to 90% of human malignancies, including SCCHN. Expression of ASPH is related to cancer cell growth, invasiveness, and disease progression through the Notch signaling pathway. As SCCHN tumors are often lacking intratumoral CD8 T cells, we believe that the addition of SNS-301 has the potential to generate and expand ASPH specific anti-tumor T cells and thereby enhance PD-1 blockade activity.

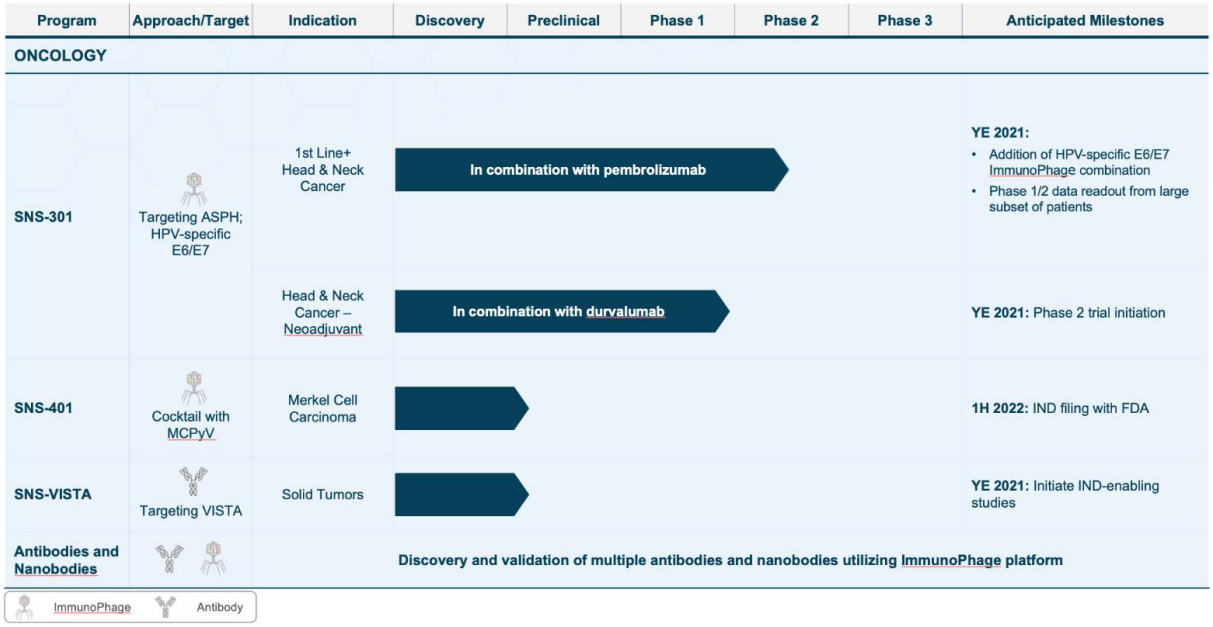
We are currently evaluating SNS-301 in combination with the PD-1 inhibitor pembrolizumab in a 30-patient Phase 1/2 clinical trial. As of March 9, 2021, we have enrolled 17 patients in the trial. As of December 10, 2020, we have evaluated ten patients for efficacy and ten for safety. The trial includes patients with locally advanced unresectable or metastatic SCCHN who have been treated with PD-1 blockade for at least 12 weeks with the best overall response being SD or unconfirmed progressive disease, or PD. Patients who achieved a PR, complete response, or CR, or confirmed progression on PD-1 blockade, are not eligible. Based on an initial assessment of the ten evaluable patients, SNS-301 in combination with pembrolizumab has been well tolerated and has shown promising anti-tumor activity, including a PR in one patient with a PD-L1 negative tumor who achieved SD as best overall response on PD-1 inhibition alone as well as SD in six patients. Of the six SD patients, one patient previously had PD on PD-L1 inhibition and two patients have achieved longstanding SD for greater than 36 weeks following treatment. We anticipate reporting a large additional subset of data from this trial by the end of 2021. If the results of this trial are positive, subject to feedback from the FDA, we intend to initiate a randomized, registration-enabling trial for SNS-301.

Based on the results we have observed to date, we have commenced enrollment of patients in an additional treatment arm of our ongoing Phase 1/2 trial to evaluate the addition of SNS-301 to pembrolizumab in PD-1 blockade naïve SCCHN patients. We intend to use an ImmunoPhage cocktail targeting the E6/E7 antigens of HPV, in combination with SNS-301, in HPV positive patients in our ongoing trial of SNS-301, which we expect to incorporate in 2021. In addition, we are currently planning a Phase 2 trial to evaluate the safety and efficacy of SNS-301 in combination with durvalumab for patients with locally advanced resectable SCCHN in the neoadjuvant setting. We intend to initiate the first trial in patients with locally advanced resectable SCCHN in the neoadjuvant setting in 2021.

In addition to SNS-301, we are currently developing our next ImmunoPhage candidate, SNS-401, for the treatment of MCC. We plan on submitting an IND for SNS-401 in 2022. We are also developing a mAb therapy targeting VISTA. Through the use of proprietary functional and in vivo assays, we intend to select a product candidate and initiate IND-enabling studies for our lead mAb by the end of 2021.

Our Pipeline

We are utilizing our pioneering ImmunoPhage platform, which harnesses the intrinsic immunostimulatory characteristics and capabilities of bacteriophage, to develop a pipeline of product candidates with an initial focus on treatments for cancer. We have worldwide commercial rights for each of our product candidates. Our current portfolio of therapeutic initiatives is presented in the diagram below:



Our Approach to Immunotherapy

Our ImmunoPhage Platform

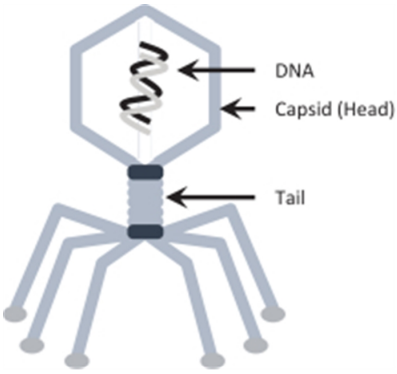
We believe that the unique features of bacteriophage give it the potential to be used in the development of differentiated treatments for cancer. The pioneering work with bacteriophage documented in scientific literature describes its potential utility as a powerful, self-adjuvanted immunotherapy platform. However, we have not directly evaluated our ImmunoPhase platform in clinical trials beyond those described below. We selected bacteriophage because of its native immunostimulatory capabilities, large and tractable genome, and tolerability profile. The highly immunogenic nature of bacteriophage promotes a balanced, coordinated and robust response by both the innate and the cellular and humoral components of the adaptive immune system. Bacteriophage has the ability to generate both T cell responses and B cell mediated antibody responses.

The bacteriophage lambda, or lambda phage, is the foundation of our ImmunoPhage platform. Lambda phage is composed of an icosahedral head, or capsid, consisting of major capsid proteins gpD and gpE that surround a single copy of a 48.5 kb double-stranded DNA genome and a flexible tail structure. The gpD protein forms specialized structures on the capsid that results in over 400 copies of the protein being displayed on the capsid surface, which can be modified with antigens to increase the antigen presentation capacity of the phage. The lambda phage DNA genome contains abundant CpG sequence motifs, which are known to function as potent APC activators, through TLR9-mediated signaling.

As bacteriophages are ubiquitous, patients either have pre-existing anti-phage antibody titers or quickly develop anti-phage antibodies upon repeat dosing. However, rather than contributing to neutralization, as is experienced with many viral and protein-based therapies, the presence of phage antibodies may augment ImmunoPhage activity through a process known as antibody-dependent enhancement, or ADE.

In addition to its natural characteristics, lambda phage can be manufactured without significant difficulty and is amenable to further optimization through our proprietary engineering capabilities, such as the addition of antigens and integration of our proprietary nanobodies, which can be used to direct the phage to specific cells and as payloads that can be incorporated into our product candidates.

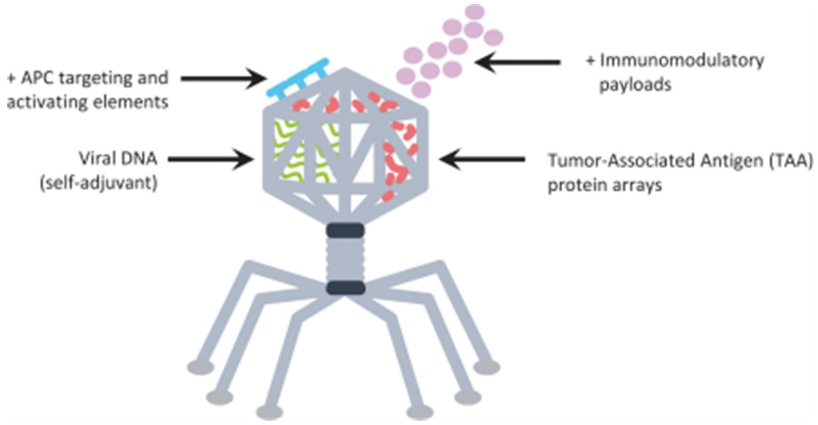
Structure of Lambda Phage



Our ImmunoPhage platform capitalizes on the following key immunostimulatory features:

- **Self-adjuvanted:** ImmunoPhage elicits an enhanced immune response and displays a high-density of the protein sequence of the targeted antigen and contains multiple CpG motifs in its DNA genome, eliminating the need to include an exogenous adjuvant common to competing viral and mRNA nanoparticle immunotherapies.
- **Intrinsic APC targeting:** ImmunoPhage demonstrates a natural tropism for APCs. We have identified and are advancing additional mechanisms, such as engineering moieties on ImmunoPhage targeted to proteins found on APCs, to further optimize APC targeting and costimulatory signaling.
- **Modular antigen design:** We intend to use off-the-shelf common antigens together with viral and patient-specific antigens as an array of customized, multi-antigen phage configurations, which we refer to as phage cocktails. We believe that the ability to dose cocktails of ImmunoPhage displaying different antigens have the potential to create a personalized, patient-specific immunotherapy.
- **Targeted use of nanobodies:** We are developing nanobodies targeted to immune checkpoints and other immune stimulatory molecules that can be packaged into the phage as immunomodulatory payloads to enhance immunogenicity.

Structure of Our ImmunoPhage

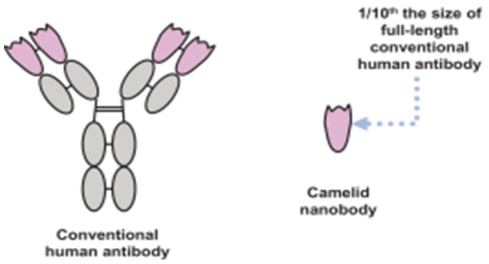


Our proprietary nanobodies, derived from alpacas, are antibody-like structures that consist of a single monomeric variable domain located on the heavy chain. Nanobodies are small (approximately 1/10 the size of mAb), robust protein-binding molecules that we believe represent the optimal class of molecules for use as immunomodulatory proteins, where payload space in a delivery vector or vehicle is limited. Like conventional antibodies, nanobodies can bind selectively to a specific antigen, but they possess additional advantages to conventional antibodies, including:

- **Small size:** Provides better access to binding grooves and contours on proteins on target cells.
- **Stability:** Stable at a wide range of temperatures and able to refold properly at varying temperatures.

- **High Solubility:** Hydrophilic, single-chain structure allows nanobodies to avoid aggregation issues common to mAbs.
- **Ease of manufacturing:** Easier and less expensive to produce due to benefits from improved screening and isolation techniques and bacterial cell production.

Size of Conventional Human Antibody versus Camelid Nanobody

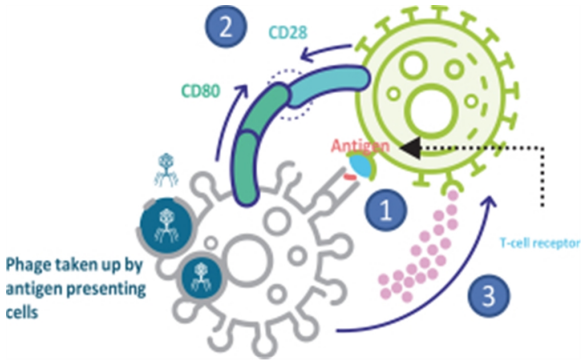


We maintain the ability to produce our customized nanobodies in-house that are compatible with our ImmunoPhage engineering processes. Our product candidates are able to be manufactured through the well-established principles of bacterial fermentation, which provides cost and scalability advantages. We can achieve GMP manufacture of an ImmunoPhage dose configuration in-house in as little as four weeks. We believe that these advantages, along with the long-term stability of ImmunoPhage, make personalized ImmunoPhage cocktails a commercially viable solution to the current challenges facing fully personalized patient-specific immunotherapy.

ImmunoPhage Mechanism of Action

Our mechanism of action focuses on what we believe to be the critical step leading to the generation of effective anti-tumor T cells, the immune priming step where APCs acquire and process tumors antigens, and interact with CD4 and CD8 T cells in the immune synapse. ImmunoPhage mimics a pathogenic virus and naturally targets APCs that capitalize on phage-intrinsic danger signals which activate these critical cells. The aggregation of antigen and danger signals enable self-adjuvant capabilities in a single entity which help to enhance the immunogenicity and augment downstream immune responses, including antigen-specific B and T cell responses. In order to drive optimal generation of antigen-specific T cells, the APC must deliver three discrete critical signals to the T cell, as shown below.

ImmunoPhage Activates Three Discrete Critical Signals Required to Drive Activation of T Cells



1 **Signal one** involves antigenic peptides, derived from APC protein processing pathways, presented in the context of the appropriate major histocompatibility complex, or MHC, molecules, Class II for CD4 T cells and Class I for CD8 T cells. An alternate MHC Class I presentation pathway results in the activation of CD8 T cells through a process called cross presentation.

2 **Signal two** involves the APC expressing positive costimulatory molecules CD80 (or CD86) interacting with CD28 on the T cells. In the presence of significant negative costimulatory signals through molecules like PD-L1 or VISTA, or the lack of sufficient positive co-stimulation, the interaction between APC and T cell can lead to dysfunction of the T cell rather than T cell activation.

3 **Signal three** collectively refers to the cytokine microenvironment of the immune synapse wherein the priming interaction between APC and T cell is occurring. This cytokine milieu determines the differentiation and fitness of the downstream T cell response. For instance, a rich IL-12 environment leads to a Th1 biased immune response and enhanced generation of CTLs.

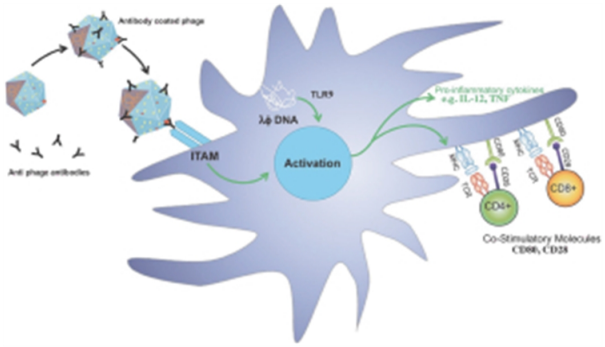
We believe that ImmunoPhage can efficiently deliver antigen to and activate DCs, driving these three critical signals in the priming phase of the immune response. We have observed that increasing doses of ImmunoPhage on human skin-derived DC cultures increase the critical components of signals two and three in a dose-dependent fashion. Importantly, in the context of anti-tumor immune responses, which require the generation of tumor antigen-specific CD8 T cells, phages can drive cross-presentation of displayed antigens, even breaking tolerance to "self" TAAs.

Since the development of pembrolizumab and other inhibitors of the PD-1 signaling pathway, it has become clear that a prerequisite for response to PD-1 blockade is the presence of a sufficient number of tumor-specific T cells, particularly, CD8 T cells in the TME. Patients with poorly immunogenic tumors lacking CD8 T cells represent a major unmet medical need. We believe that there is a significant opportunity for our ImmunoPhage platform to drive the generation of tumor antigen-specific T-cells and potentially convert PD-1 blockade non-responders into responders.

To optimize immunotherapy in cancer, a two-fold approach may be required: the first is the systemic generation of antigen-specific T cells through vaccination or adoptive transfer and the second refers to inhibition of immunosuppressive mechanisms limiting the entry of T cells into the TME. In situ vaccination has been shown to "soften" the TME and increase T cell infiltration. We believe that ImmunoPhage delivered to the tumor, either by direct intralesional injection or by the development of tumor-targeted phages, can deliver both a potent generation of tumor-specific T cells and enhancement of T cell infiltration into tumors.

In addition to our ImmunoPhage-based approach, we are developing a human mAb targeting the immunosuppressive VISTA checkpoint protein as well as nanobody programs targeting other key molecules preventing T cell entry into the TME and cytotoxic activity, including TGFb, IL-10 and PD-1. The goal of these programs is to limit the immunosuppressive mechanisms that prevent T cell entry into the TME.

ImmunoPhage leverages anti-drug antibodies that limit the use of other viral and protein-based therapies to enhance immunogenicity. ADE occurs when anti-phage antibodies which coat the capsid surface result in enhanced uptake by, and activation of, DCs through the binding and activation of Fc receptors, or FcRs. The high-density of phage-bound antibody is thought to lead to massive cross-linking of certain FcRs, leading to a strong immunogenic response to FcR-mediated endocytosis of the phage antigen/antibody complex. This mode of DC activation can lead to enhanced T cell responses, including CD8 priming by enabling cross-presentation.



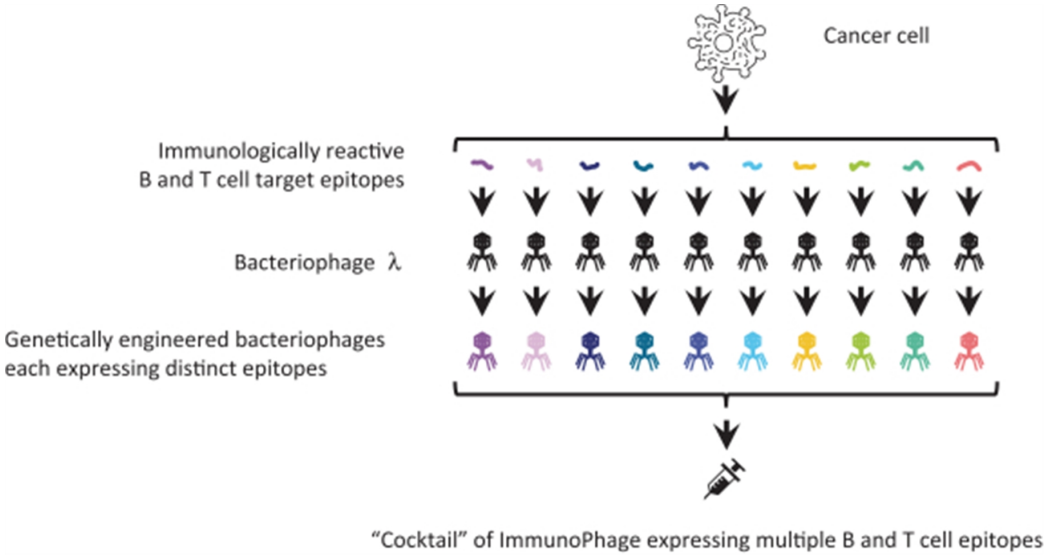
Our Adaptive Approach to ImmunoPhage Cocktail Therapy

Our ImmunoPhage platform enables a cocktail therapy approach that has the potential to provide patients with the benefits of both an off-the-shelf treatment and a personalized approach to their individual cancer. Each ImmunoPhage product candidate we produce has a unique therapeutic armament, such as various multivalent antigens, including those targeting CD4, CD8 and B cell epitopes designed to deliver broad epitope coverage, and nanobody payloads added to boost antigenicity or provide direct cancer cell killing capabilities. Based on the profile of a patient's tumor, multiple distinct ImmunoPhage product candidates, each having a distinct profile, can be combined for treatment. We believe that broad epitope coverage along with nanobody payloads, combined with the intrinsic immunostimulatory activity of our ImmunoPhage product candidates, can provide patients a therapy with meaningful clinical benefits.

The modular nature of the Phortress library allows for personalized dynamic substitution of particular ImmunoPhage components to optimize patient therapy. Moreover, the ease of manufacturing allows us to perform immune monitoring in patients to assess the immunogenicity of each phage component of a cocktail and adjust the cocktail during the course of treatment. To date, we have constructed over 25 unique ImmunoPhage configurations and anticipate expanding our Phortress library as we advance our clinical stage programs.

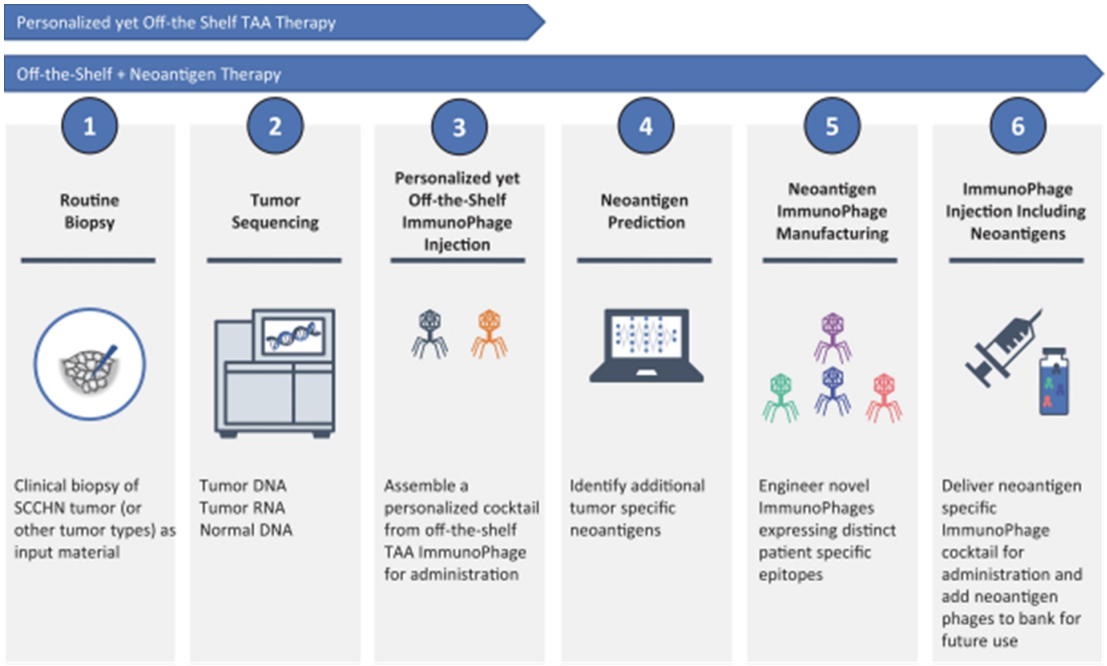
We also intend to utilize the potential of an adaptive cocktail therapy approach in our ongoing and future clinical trials, including in our SNS-301 and SNS-401 programs. We have discussed the proposed clinical trial design, including the adaptive cocktail therapy approach, with the FDA. We believe this strategy will allow us to use insights derived from initial study cohorts, such as antibody titers raised against a target antigen, to dictate phage substitutions to the phage cocktail which are subsequently tested in additional cohorts. The best performing cocktail can then be advanced into dose expansion and later-stage clinical trials.

ImmunoPhage Adaptive Cocktail Therapy Approach



We believe that the speed of manufacturing and antigenic capacity of ImmunoPhage cocktails will allow us to address the limitations of neoantigen-only vaccine approaches. With the Phortress library, we have the ability to quickly initiate an off-the-shelf immunotherapy with a patient-specific ImmunoPhage cocktail from our shared antigen library within 1 to 2 weeks of diagnosis as display in steps 1 through 3 in the figure below, and then to augment the cocktail with a newly designed neoantigen phage within 4 to 6 weeks, as displayed in steps 4 through 6 below. We believe that this approach has the potential to address the urgency of treatment and provide the patient with an enhanced anti-tumor immune response.

Our Personalized Immunotherapy Process



SNS-301: Our Lead ImmunoPhage Candidate Targeting ASPH for Treatment of SCCHN

Our lead product candidate, SNS-301, is an ImmunoPhage construct engineered to generate a strong, specific immune response against the TAA ASPH. We believe the immune stimulatory effects generated by our ImmunoPhage platform, combined with the inhibition of the PD-1 immune system checkpoint, act in a complementary manner to produce an enhanced immune response in SCCHN patients. SNS-301 is being studied in an ongoing Phase 1/2 trial in combination with pembrolizumab. As of December 10, 2020, ten patients were evaluable for efficacy. Of these patients, we have observed that SNS-301 in combination with pembrolizumab has been well tolerated and has shown promising anti-tumor activity, including a PR in one patient with a PD-L1 negative tumor and disease control in seven of ten evaluable patients.

Head and Neck Cancer

Head and neck cancer is the sixth most common malignancy worldwide, accounting for approximately 6% of all cancer cases, and is responsible for an estimated 1% to 2% of all cancer deaths. Head and neck cancers encompass an array of cancers originating in the squamous cells that line the moist, mucosal surfaces inside the head and neck. More than 90% of head and neck cancers are classified as squamous cell carcinomas that raise from the mucosal surfaces of the oral cavity, oropharynx and larynx.

An estimated 650,000 cases of head and neck cancer are diagnosed annually worldwide, including approximately 50,000 cases in the United States, with more than 350,000 deaths annually worldwide. HPV infection accounts for an estimated 70% of SCCHN cases in the United States. The primary causes of SCCHN are smoking, heavy alcohol use and certain types of HPV.

Early-stage head and neck cancer is typically either treated with surgery or radiation alone; however, approximately 66% of patients present with advanced disease and fewer than 30% of these are cured. The management of advanced disease consists of multiple-modality therapy with surgery, radiation, chemotherapy and immunotherapy. Despite improvements in diagnoses and local management, long-term survival rates for patients with SCCHN have not increased significantly over the past 30 years and are among the lowest when compared against other major cancers.

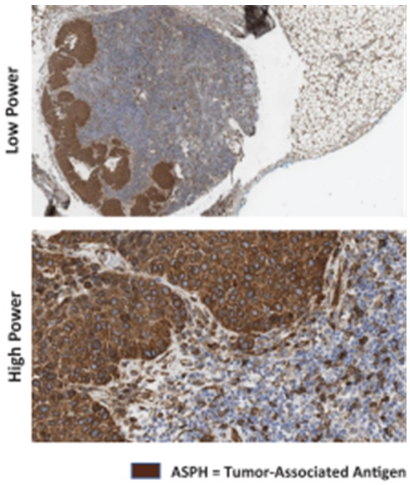
Targeting ASPH

ASPH is a TAA, strongly expressed in 70% to 90% of human malignancies, including carcinomas, such as SCCHN, and sarcomas and hematologic malignancies. Expression of ASPH is related to cancer cell growth, invasiveness, and disease progression

through the Notch signaling pathway. SNS-301 is designed to overcome self-tolerance and induce robust and durable humoral and cellular immune responses that target tumors expressing ASPH.

In the course of conducting our ongoing Phase 1/2 trial for SNS-301, we collected ASPH-positive tumor samples from 30 patients who had been screened for inclusion in our trial, although some patients who had samples collected did not satisfy other criteria for ultimate inclusion in our trial. The samples were stained to show intratumoral ASPH expression. Depicted below is a staining of a representative patient's tumor biopsy using an immunohistochemistry assay. The first figure shows the magnification at low power, while the second figure shows the same sample at a higher power of magnification. In each figure, the ASPH is shown in the darker color.

Representative Patient ASPH-Positive Tumor Sample



SNS-301—A Potential Solution for SCCHN

We believe that SNS-301, in combination with pembrolizumab, has the potential to produce enhanced activity in patients with SCCHN compared to currently available therapies. We are developing SNS-301 for the treatment of SCCHN due to the cancer's lack of intratumoral T cells and the consequent modest objective response rate to PD-1 blockade. We selected SCCHN as our first indication based on a high unmet need, a clearly defined regulatory path and easily accessible tumor for obtaining biopsies for early translational data to evaluate immune activation.

Although drugs utilizing PD-1 blockade have been approved for several years in the treatment of advanced SCCHN after platinum containing chemotherapy, the objective response rate, or ORR, has been reported to be as modest as 13% to 18% in relapsed or refractory SCCHN patients with progression free survival, or PFS, of two months and overall survival, or OS, of eight months. Objective responses predominantly occur in patients with PD-L1 positive tumors, with demonstrated ORR of 21% for PD-L1 positive patients, while patients with PD-L1 negative tumors are reported to have a response rate of only 6%. Pembrolizumab has been approved for use as a first-line therapy in combination with chemotherapy for all patients and as a single agent for patients with PD-L1 positive of T cells infiltrating the tumor. As SCCHN tumors are often lacking intratumoral CD8 T cells, we believe that the addition of SNS-301 has the potential to generate and expand ASPH specific anti-tumor T cells and thereby enhance PD-1 blockade activity.

SNS-301: Ongoing Phase 1/2 Trial Status and Design

We are currently conducting an open-label, multi-center Phase 1/2 clinical trial of SNS-301 in combination with pembrolizumab. The primary objectives of this trial are to assess the safety and tolerability of SNS-301 in combination with pembrolizumab and the anti-tumor activity of the combination treatment as measured by ORR, PFS per iRECIST and OS. The secondary objective is to assess the preliminary immune response, which is measured by evaluating antigen-specific antibody and T cells and other lymphocytes. Examination of paired pre- and post-treatment biopsy samples are being utilized to evaluate whether the addition of SNS-301 to PD-1 blockade results in increased inflammation, determined by the presence of TILs, PD-L1, inflammatory gene signatures. As of March 9, 2021 we have enrolled 17 patients in the trial. As of December 10, 2020, we have evaluated ten patients for efficacy and ten for safety. Our Phase 1/2 trial includes patients with locally advanced unresectable or metastatic SCCHN who have been treated with PD-1 blockade for at least 12 weeks with the best overall response being SD or unconfirmed PD based on

RECIST1.1 and iRECIST, industry accepted standard guidelines for tumor evaluation. RECIST 1.1 defines a CR, PR, SD and PD as follows:

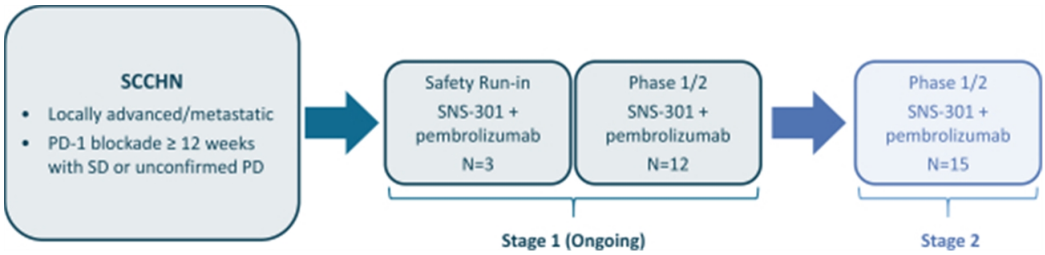
Category	Description
Complete Response (CR)	Disappearance of all Tumor Lesions
Partial Response (PR)	Reduction of ≥30% of the Sum of Target Diameters
Stable Disease (SD)	Reduction of <30% or increase of <20% of the Sum of Target Diameters
Progressive Disease (PD)	Increase of ≥20% of the Sum of Target Diameters

Patients who achieved a PR, CR or confirmed progression on PD-1 blockade are not eligible for participation in this clinical trial. The rationale for this restrictive inclusion criteria is based on reported data demonstrating that the median time to a PR or CR with PD-1 blockade is two months. Therefore, by excluding patients that achieved PRs or CRs while on PD-1 blockade alone for at least 12 weeks, we believe that any PRs or CRs observed in our Phase 1/2 trial are likely attributable to the addition of SNS-301. Similarly, we believe that a patient with PD on single-agent PD-1 blockade achieving stabilization after the addition of SNS-301 is an indication of clinical benefit from the treatment combination.

Phase 1/2 trial design

The treatment regimen consists of repeat doses of SNS-301 administered intradermally on Day 0, Week 3, Week 6, Week 9, then every 6 weeks for 6 additional doses, and thereafter every 12 weeks until confirmed disease progression, unacceptable toxicity, patient intolerability as determined by the investigator or up to 24 months in patients without disease progression. Pembrolizumab is administered intravenously as per standard of care at either 200 mg every 3 weeks or 400 mg every 6 weeks.

Design of the Phase 1/2 Clinical Trial of SNS-301 in SCCHN



The Phase 1/2 trial consists of a safety run-in followed by a Simon two-stage design in the absence of any dose-limiting toxicities, or DLTs, during the safety run-in, with a total initial enrollment of 15 patients, which we refer to as Stage 1. The trial design allows additional expansion up to a total of 30 patients if one CR or PR is observed in Stage 1. We did not observe any DLTs during the safety run-in and are continuing to enroll patients through Stage 1. Since one patient in our clinical trial has already achieved a confirmed PR, as described below, the pre-defined efficacy criteria of Stage 1 has been met, allowing us to continue into Stage 2 and dose up to a total of 30 patients in the trial.

Ongoing Phase 1/2 Trial Results

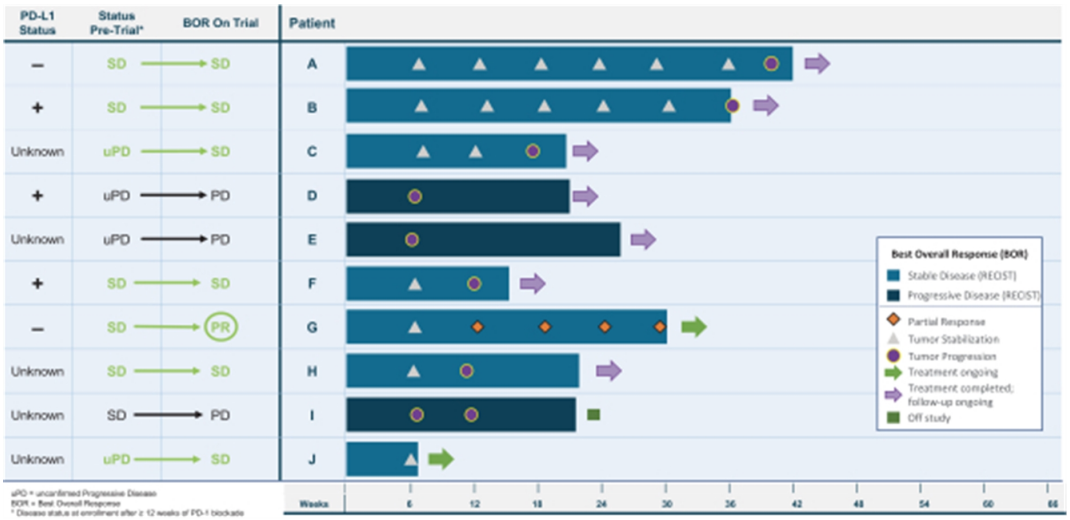
Preliminary evidence of clinical benefit of SNS-301 in combination with pembrolizumab

As of the December 10, 2020 data cutoff for the first 11 patients in Stage 1 of our ongoing Phase 1/2 trial, we observed the following results in the first ten patients evaluable for efficacy:

- PR in one patient with a PD-L1 negative tumor who previously achieved SD on PD-1 inhibition alone;
- SD in six patients, including:
  - one patient that has achieved SD for more than 4 months following PD at enrollment after 10 months of PD-L1 blockade treatment; and
  - two patients with longstanding SD for 9 and 9.5 months, respectively, of which one SD occurred in a patient with a PD-L1 negative tumor; and
- PD in three patients, including two patients who had PD at enrollment while on PD-1 blockade.

One patient withdrew consent prior to the first efficacy evaluation and was therefore not evaluable for efficacy. As shown in the figure below, disease control, as evidenced by PR or SD, was achieved in seven of the ten patients regardless of HPV status. Tumor regression was observed regardless of PD-L1 or HPV status.

Duration of Response in Ongoing Phase 1/2 Trial of SNS-301 in Combination with Pembrolizumab



Patient G referred to in the chart above achieved a PR at 12 weeks. This patient was diagnosed in May 2018 with HPV negative and PD-L1 negative SCCHN. At diagnosis, the cancer was classified as Stage II and graded T2N0M0, an enlarged tumor (<4 cm) that had not spread to lymph nodes or other organs. This patient received radiation therapy followed by two cycles of platinum-based chemotherapy, achieving a PR. At the time of enrollment into this trial, the patient had received pembrolizumab for more than 12 weeks with SD. After six weeks on SNS-301 in combination with pembrolizumab, the combined lesion measurement had decreased by 29%. After 12 weeks, the combined lesion measurement had decreased by 43% from baseline, achieving a PR that was confirmed at the 18-week scans. Furthermore, the 30 week scan showed an additional decrease to 52%, maintaining a PR.

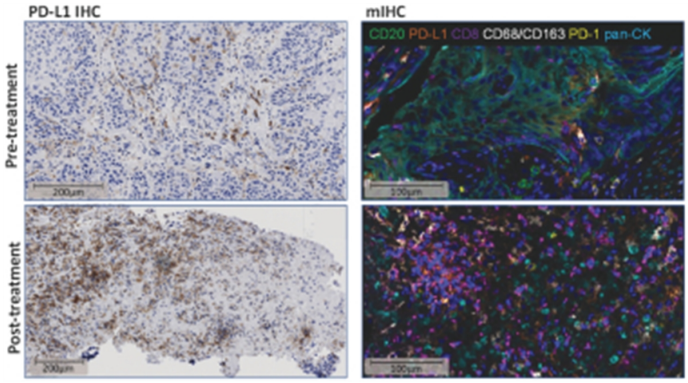
Patient C is another patient of notable clinical interest who had been treated with the PD-L1 inhibitor atezolizumab for 10 months when scans showed PD per RECIST 1.1. After receiving combination therapy with SNS-301 and pembrolizumab, two consecutive scans six weeks apart showed SD. Given that SCCHN is an aggressive disease, we believe stabilization of an ongoing progression suggests that SNS-301 likely added to the improvement of the patient's disease status. Safety concerns related to COVID-19 prevented the acquisition of paired biopsies to evaluate the TME in this patient.

In addition, of the two Patients (A and B) with longstanding SD of 9 and 9.5 months, respectively, Patient A's tumor was assessed as PD-L1 negative in the clinical setting.

Translational Data Demonstrated T Cell Integration into the Tumor Supporting Antitumor Activity of SNS-301

A comparison of pre-treatment and on-treatment biopsies showed a definitive increase in PD-L1 expression, which likely represents an influx of T cells into the TME and aligns with the achieved clinical benefit. As illustrated below, a predominance of tumor cells was observed pre-treatment, with a pronounced influx of immune cells noted upon treatment. Multiplex IHC demonstrates that the PD-L1 staining in the post-treatment biopsy is found in close proximity to PD-1 positive CD4 and CD8 TILs.

SNS-301 Catalyzes Conversion of PD-L1^{NEG} Immune Desert Tumor into Inflamed Phenotype in Patient with PR



Given that the patient initially had a PD-L1 negative tumor with no objective response to PD-1 blockade alone and that after combination treatment the patient achieved a PR with transformation of the tumor into a PD-L1 positive inflamed phenotype, we believe the additional treatment benefit is likely attributable to the addition of SNS-301. Serology data indicated the presence of anti-phage antibodies prior to treatment, suggesting increased immunogenic activity related to ADE.

SNS-301 in Combination with Pembrolizumab has been well tolerated

As of December 10, 2020, based on the 11 patients enrolled in our ongoing Phase 1/2 trial, the combination of SNS-301 and pembrolizumab has been generally well tolerated. No DLTs have been observed in the safety run-in and observed adverse events, or AEs, have primarily been either Grade 1 or 2 or unrelated to treatment. Three Grade 3 related AEs, dehydration, electrocardiogram QT prolongation and rash, have been reported. Four serious adverse events, or SAEs, have been reported. The Grade 3 dehydration was also an SAE as a result of hospitalization; however, it was attributed to an underlying cancer and concomitant medication by the sponsor, and therefore not a reportable event. One patient experienced an SAE for Grade 2 hemoptysis and two weeks later a second SAE of Grade 2 dehydration. Neither of these events were considered related to study drug, but were instead attributed to disease progression. There was one SAE of Grade 2 systemic inflammatory response syndrome that occurred during the follow-up visit but was assessed as not being a treatment-related adverse event.

SNS-301: Future Clinical Plans

We expect to report a large subset of data from the Phase 1/2 trial by the end of 2021. If the results from our Phase 1/2 trial are positive, subject to feedback from the FDA, we intend to initiate a randomized, registration-enabling trial of SNS-301 against standard of care, single-agent pembrolizumab.

Based on the results we have observed to date, we have commenced enrollment of patients in an additional treatment arm of our ongoing Phase 1/2 trial to evaluate the addition of SNS-301 to pembrolizumab in PD-1 blockade naïve SCCHN patients.

We also intend to use an ImmunoPhage cocktail targeting the E6/E7 antigens of HPV, in combination with SNS-301, in HPV positive patients in our ongoing trial of SNS-301, which we expect to incorporate in 2021. As a significant percentage of SCCHN patients are HPV positive, we believe the opportunity to incorporate our HPV-specific E6/E7 ImmunoPhage into a combination with SNS-301 has the potential to increase the evidence of clinical benefit seen to date.

We entered into a clinical trial collaboration with AstraZeneca in May 2019 to evaluate the safety, tolerability and preliminary efficacy of AstraZeneca's PD-1 inhibitor, durvalumab, in combination with SNS-301. Under the agreement, AstraZeneca will be supplying us with durvalumab for the trial with no upfront, milestone or royalty payments required by us. We intend to initiate a first trial under this collaboration in patients with locally advanced resectable SCCHN in the neoadjuvant setting in 2021.

Prior Clinical Results

In 2018, we completed a Phase 1 trial evaluating the safety, immunogenicity and efficacy of SNS-301 in patients with biochemical relapse of localized prostate cancer after surgery or radiotherapy. SNS-301 was dosed intradermally in three cohorts of patients, using a fixed dose escalation scheme every 21 days to establish the maximum tolerated dose, or MTD. Patients who tested positive for ASPH in either tumor tissue or serum were eligible to continue in the study. The treatment regimen consisted of three repeat doses of SNS-301 at each dose level (2.0×10^{10}, 1.0×10^{11} and 3.0×10^{11} particles) administered intradermally every 21 days

for nine cycles plus six months of follow up. Three patients were enrolled in the low and mid dose cohorts and six patients were enrolled in the high dose cohort.

SNS-301 was well tolerated in the trial, with few and mostly mild AEs, no observed DLTs and no patients experiencing study drug related SAEs or Grade 4 or Grade 5 AEs. Importantly, there were no indications of an off-target autoimmune response. Furthermore, the MTD of SNS-301 was not reached. Three major protocol deviations occurred during the study: two patients went from middle to high dose prematurely of which one stayed at the higher dose level and one patient varied between middle and high dose levels in subsequent cycles, and one patient (assigned to the lowest dose level) was started on the excluded anti-androgen drug bicalutamide after one year on study treatment. Of the 12 treated subjects, nine discontinued the study before completing all protocol required assessments: six because of sponsor decision, one due to investigator decision, and one with prostate-specific antigen doubling time <90 days and one from an AE (severe arthralgia not related to study drug).

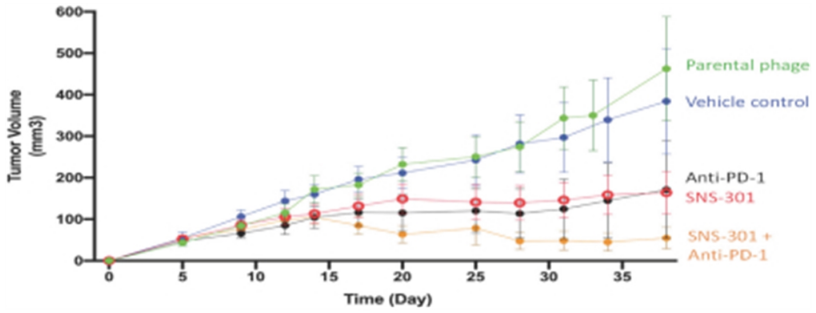
All patients had antigen-specific immune responses, with SNS-301 inducing a multi-variate immune response including T cells and B cells in the majority of patients. In addition, seven of the 12 participants in this Phase 1 safety trial, or 58%, demonstrated a reduction in the doubling time of biomarker prostate specific antigen, or PSA, levels through cycle 2. The second dosage level of 1.0 x 10^{11} was chosen as the recommended Phase 2 dose based on safety, immunogenicity data and the observation of an improvement in PSA doubling time for the mid-dose patients (two of three patients) compared to the high dose (three of six patients).

Preclinical Study Results

SNS-301 was evaluated in rodents for immunogenicity and efficacy. Immunogenicity was observed in mice and rats, with both humoral and cellular immune response specific to ASPH to the amount of and number of doses. Efficacy data was obtained in three rodent tumor models, BNLT3, 4T1 and MLLB-2, showing inhibition of tumor and or metastasis growth. A repeat dose toxicology study in rats has been conducted with no adverse safety findings for SNS-301.

As illustrated in the graph below, in a murine model of hepatocellular carcinoma, co-administration of SNS-301 and a PD-1 inhibitor resulted in a significant decrease in tumor growth, as did administration of SNS-301 or an anti-PD-1 antibody individually. We believe the results of this study provide encouraging evidence that checkpoint inhibition removes immunological encumbrances while at the same time SNS-301 works to drive antigen-specific immune activation.

SNS-301 and PD-1 Blockade Slowed Tumor Growth in a Liver Cancer (Hepa 1-6) Treatment Model



SNS-401: Our ImmunoPhage Candidate Targeting Merkel Cell Carcinoma

We are currently developing our next ImmunoPhage candidate, SNS-401, for the treatment of MCC. MCC is a rare but highly aggressive neuroendocrine carcinoma of the skin in which MCPyV infection and chronic exposure to ultraviolet radiation are key risk factors. Approximately 2,500 cases are diagnosed each year with the disease-specific mortality approaching 50%. Integration of MCPyV is evidenced by the presence of virus-specific epitopes in 80% of cases diagnosed in the U.S. In these cases, expression of a virus-related T cell oncogenic antigen appears intimately linked to tumor growth.

Checkpoint inhibitors have proven to be a major advancement in the treatment of advanced MCC and have revolutionized the treatment of locally advanced, inoperable and metastatic MCC. Systemic PD-1/PD-L1 inhibition therapy is associated with a high ORR, prolonged durable responses, and good tolerability in advanced-stage MCC. However, even with the advances made by checkpoint inhibitors, refractory PD-1/PD-L1 inhibitor disease remains a significant unmet medical need with an aggressive clinical course.

In March 2020, we established an exclusive exploratory collaboration with The University of Washington, one of the world's leading research centers for the study of MCC. This collaboration provides for the joint construction, to the preclinical development stage, of the first custom MCC vaccine consisting of MCPyV epitopes together with other patient specific antigens. There are no upfront, milestone or royalty payments payable to either party as part of this collaboration. The University of Washington will design MCPyV T cell constructs and determine the immunogenicity and mechanism of candidate ImmunoPhages developed by us. We will develop ImmunoPhages specifically targeting MCPyV T cell constructs and other TAAs using our cocktail approach. We believe that the MCPyV epitope space can be completely addressed with an ImmunoPhage cocktail of two bacteriophage carriers. We have an option to license on an exclusive, worldwide basis the intellectual property developed as part of this collaboration. Currently, we plan on submitting an IND for SNS-401 in 2022.

SNS-VISTA: Monoclonal Antibody targeting VISTA

We are developing a mAb therapy targeting VISTA. VISTA is an immunoregulatory receptor and is highly expressed on various immune system cells including neutrophils, monocytes, macrophages, basophils and DCs. While highly expressed on CD4 T helper cells and certain T regulatory cells, it exhibits much lower expression on CD8 CTLs.

VISTA is an important checkpoint regulator. Effective PD-1 blockade is often confounded by alternative immune checkpoints, such as VISTA, and we have chosen to develop a mAb targeting VISTA in the expectation that our development of this checkpoint inhibitor will closely complement our ImmunoPhage development activities. Unlike other checkpoint regulators, which are induced after activation, VISTA expression is maintained at a steady state. This broad pattern of expression suggests that VISTA has an important role in regulating immune system activity and preserving homeostasis. VISTA's presence in tumors is often indicative of a poor prognosis. Analysis of the TME often reveals an absence of TILs as well as a reduction in cytokines and other co-stimulatory molecules. VISTA blockade appears to dramatically modulate the TME towards a state that favors an immune system response, resulting in improved T-cell effector function and anti-tumor activity. Accordingly, VISTA has been identified as a promising therapeutic target.

In January 2020, we entered into a collaborative agreement with AdiMab to expedite antibody development through the production of human IgGs that we may evaluate as potential therapeutic product candidates. Under this agreement, we provide key proprietary reagents and information to AdiMab to enable the initiation of antibody discovery and development. In March 2020, AdiMab initiated our VISTA antibody campaign. In June 2020, we received a first shipment of 84 IgGs for further screening. Among these, several have passed through our proprietary screening criteria and we believe multiple antibodies possess the desired biophysical properties and mechanism of action for a potential clinical candidate. Through the use of proprietary functional and in vivo assays, we intend to select a product candidate and initiate IND-enabling studies for our lead mAb by the end of 2021.

Manufacturing

We have manufactured SNS-301 bulk drug substance for clinical trials, as well as our current Phortess library, at our own manufacturing facility. We are in the process of establishing a new manufacturing facility, which will further enable production of drug substance under cGMP conditions. We believe that having control over the manufacturing process allows us to reduce cycle times, increase the robustness and consistency of the process and potentially reduce cost of goods for commercial production, which are critical to the construction of our Phortress library consisting of multiple novel ImmunoPhage. We expect that having a dedicated manufacturing facility will allow us to optimize commercial-scale processes and to develop a suitable workforce capable of supporting market launch. As we advance into later-stage clinical trials and additional indications, we intend to expand our current manufacturing capabilities to support larger scale clinical trials and the potential commercialization of our product candidates.

We may also rely on contract manufacturing organizations, or CMOs, to produce our product candidates for clinical use. We require that our CMOs produce bulk drug substances and finished drug products in accordance with cGMP, and all other applicable laws and regulations. Although we have established our own manufacturing facility, we may rely on CMOs for parts of the process, like filling and labelling of our products for commercial sale. Any agreements with potential and existing manufacturers will include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally for our clinical product SNS-301. The claims of U.S. Patent Nos. 9,744,223 and 10,702,591 encompass the clinical product. We continue to pursue claims directed to the clinical product in related applications. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form that will provide us with meaningful protection for our product. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us 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 product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. 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, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "Risk Factors—Risks Related to Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

As of March 9, 2021, our solely owned patent estate included four issued U.S. patents, two issued foreign patents, eight pending U.S. patent applications, two pending international (PCT) patent applications, and over eight foreign patent applications (pending in Canada, Europe, Hong Kong and Japan).

With regard to SNS-301, we own one pending U.S. patent application and two issued U.S. patents with composition of matter claims covering SNS-301. The issued U.S. patents and U.S. patent application, if issued, are expected to expire in 2033, subject to payment of required maintenance fees, annuities and other charges. We also own one issued European EP patent (in force in France, Germany and the United Kingdom) and five pending foreign patent applications (pending in Canada, Europe, Hong Kong and Japan), where the EP European patent and the pending foreign patent applications, if issued, are expected to expire in 2034.

We own one pending U.S. patent application and one pending, published PCT application with claims directed to methods for using and making the SNS-301 product candidate. The U.S. patent application and patent applications claiming the benefit of the PCT application, if issued, are expected to expire in 2039, subject to payment of required maintenance fees, annuities and other charges.

We own one pending U.S. patent application and one pending, published PCT application relating to methods for using the SNS-301 product candidate in combination with immune checkpoint protein inhibitors. The U.S. patent application and patent applications claiming the benefit of the PCT application, if issued, are expected to expire in 2040, subject to payment of required maintenance fees, annuities and other charges.

We own one provisional U.S. patent application relating to phage-based vaccines targeting SARS-CoV-2 proteins. Subject to payment of required maintenance fees, annuities and other charges, and assuming either U.S. non-provisional or foreign patent applications are filed at the appropriate time, if issued, are projected to expire in 2041.

We own one provisional U.S. patent application relating to phage-based vaccines targeting human papilloma virus proteins. Subject to payment of required maintenance fees, annuities and other charges, and assuming either U.S. non-provisional or foreign patent applications are filed at the appropriate time, if issued, are projected to expire in 2042.

We own one provisional U.S. patent application relating to decorated phage-based vaccines and cocktails of such vaccines. Subject to payment of required maintenance fees, annuities and other charges, and assuming either U.S. non-provisional or foreign patent applications are filed at the appropriate time, if issued, are projected to expire in 2042.

License Agreement with Fred Hutch

In connection with our acquisition of Alvaxa Biosciences, Inc., or Alvaxa, in May 2020, we acquired a non-exclusive license agreement, or the Fred Hutch Agreement, with Fred Hutchinson Cancer Research Center, or Fred Hutch, which was originally entered into in January 2020 and amended in March 2020. Pursuant to the Fred Hutch Agreement, we obtained a non-exclusive, non-sublicensable, worldwide license to possess, maintain, and use certain biological materials, including llama-derived antibodies, for any and all uses. Under the Fred Hutch Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one product containing or derived from an antibody in any form, or a developed product.

As partial consideration for the licensed rights granted under the Fred Hutch Agreement, Alvaxa issued Fred Hutch 1,429,412 shares of its common stock, which were subsequently exchanged for 45,656 shares of our common stock in connection with our acquisition of Alvaxa. Under the Fred Hutch Agreement, we are obligated to pay an annual license maintenance fee ranging from the mid-single digit thousands to approximately $0.1 million, depending on net sales of developed products in a given calendar year. We are also obligated to pay up to $300,000 in development milestone payments for each therapeutic developed product and up to $165,000 for each diagnostic developed product, in each case including each unique target covered by such developed product. We have no obligation to pay royalties under the Fred Hutch Agreement.

The Fred Hutch Agreement expires 20 years after the effective date. We may terminate the agreement for convenience, and Fred Hutch may terminate the agreement for our insolvency. Either party may terminate the agreement for breach of material obligations by such other party.

Trademarks, Trade Secrets and Know-How

Our trademark portfolio currently consists of two registered trademarks and one trademark application. In addition to patent and trademark protection, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants, and employees. These and other agreements, such as invention assignment agreements, grant us ownership of technologies that are developed through a relationship with a third party.

Competition

The biotechnology and pharmaceutical industries have made substantial investments in recent years into the rapid development of novel immunotherapies for the treatment of a range of pathologies, including cancers and infectious diseases, making this a highly competitive market.

We face substantial competition from multiple sources, including large and specialty pharmaceutical, biopharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunotherapy and, furthermore, within the treatment of cancers and infectious diseases.

In addition to the current standard of care treatments for patients with cancers and infectious diseases, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immunotherapy. Results from these studies and trials have fueled increasing levels of interest in the field of immunotherapy.

Large pharmaceutical companies that have commercialized or are developing immunotherapies to treat cancer include AstraZeneca, Bristol Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer, and Roche/Genentech.

On the technology level, other companies which can potentially develop competing product candidates which act to stimulate the body's immune response as a treatment for SCCHN and other solid tumors include companies developing cell-based therapeutics such as CAR-T/TCR/NK therapies as well as companies developing therapeutic vaccines including BioNTech, Moderna, Gritstone Oncology and Oncorus, among others. In addition, a number of companies are developing oncolytic virus approaches, including Boehringer Ingelheim, Johnson and Johnson, Regeneron, Vyriad, Replimune and Turnstone. Amgen has received FDA approval for its oncolytic virus-based product, T-VEC. Ablynx, a subsidiary of Sanofi, and Oncorus are actively pursuing the development of nanobodies as therapeutics.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors.

Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries 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 biological products. 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.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, suspension or revocation of a license, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

Our product candidates and any future biological product candidates we develop must be approved by the FDA through a biologics license application, or BLA, before they may be legally marketed in the United States. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency. The FDA review and approval process generally involves the following:

- completion of extensive preclinical studies conducted in accordance with applicable regulations, including studies conducted in accordance with good laboratory practices, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or 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;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biologic 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;
- potential FDA audit of the preclinical study and clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

Preclinical Studies and IND

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of product biological characteristics, chemistry and formulation, 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 studies, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, 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, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, 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.

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 study 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 generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap or be combined, such that the objectives of multiple phases are addressed within the design of a single trial.

- 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, pharmacologic action, side effect tolerability and safety of the product candidate. When conducted in disease-affected patients and including an endpoint of early activity or efficacy, such a trial may be a Phase 1/2 trial, comprising a Phase 1 portion and a Phase 2 portion.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. 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. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. Phase 2/3 trials may also be designed to sequentially address both dose finding and effectiveness in a single trial.

- 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 candidate and provide an adequate basis for product labeling.

In August 2018, the FDA released a draft guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the Phase 1 first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of licensure for biological products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or 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 biological product candidate 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 check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biological product candidate as well as finalize a process for manufacturing the product candidate 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, purity and potency of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then 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. The BLA may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product candidate's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational product to the satisfaction of FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. The sponsor of an approved BLA is also subject to an annual prescription drug program fee. 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 FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accepting the BLA for filing. The FDA decides whether to accept 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 ten months from the filing date in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often 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. Additionally, the FDA may refer applications for novel products or products which 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 considers 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 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 usually describes all of the specific deficiencies in the BLA identified by the FDA. The complete response letter may require additional clinical data, pivotal Phase 3 clinical trial(s) as well as other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. 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. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a 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 and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation for a biologic 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 does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. If a product that has orphan drug 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 biological 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 but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor’s product for the same indication or disease. If a biological product designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new biologics that meet certain criteria. Specifically, new biological product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening condition 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 biological product candidate can request the FDA to designate the product for fast track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting.

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. Any product candidate is eligible for priority review if it treats 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 for a new biologic designated for priority review in an effort to facilitate the review.

A product candidate may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on 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, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a biological product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a biological product candidate shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval for such biologic.

Additionally, a biological product candidate may be eligible for designation as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program.

Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product candidate for an indication for which orphan designation has been granted.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the registration-enabling trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials as well as other clinical development programs.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the

commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violations, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of post-approval problems with a product may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

U.S. Healthcare Reform and Other U.S. Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which companies sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy regulations by federal and state governments and by governments in foreign jurisdictions can apply to the manufacturing, sales, promotion and other activities of pharmaceutical manufactures. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that 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. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. 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 federal 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 FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- The anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of items or services reimbursable, whole or in part, by a federal or state governmental program;

  The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or

under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose or otherwise process individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, covered manufacturers will be required to report information regarding payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- 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; and
- 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 that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations with respect to certain laws. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Ensuring our business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. The failure to comply with any of these laws or regulatory requirements subjects companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Additionally, private individuals have the ability to bring actions on behalf of the U.S. government under the federal FCA as well as under the false claims laws of several states against a pharmaceutical manufacturer. The approval and commercialization of a pharmaceutical manufacturer's product candidates outside the United States will also likely subject it to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Lastly, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical company to incur significant legal expenses and divert management's attention from the operation of the business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must now, as amended by the Bipartisan Budget Act of 2018, effective January 1, 2019, 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 to coverage under Medicare Part D for the manufacturer's outpatient drugs.

There have been executive, judicial and congressional challenges. While Congress has not passed comprehensive repeal legislation, there have been a number of significant changes to the ACA and its implementation. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is uncertain when a decision will be reached or how the Supreme Court will rule. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020, along with other COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives which could limit the amounts that federal and state governments will pay for healthcare products and services and result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Additionally, 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 proposed and enacted federal and state 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 sought to implement several of the administration's proposals. As a result, the FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under 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 safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and result in reduced demand for our current product candidates and any future product candidates or additional pricing pressures. It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Legislative and regulatory proposals, and enactment of laws, at the foreign, federal and state levels, directed at containing or lowering the cost of healthcare, will continue into the future. Further, we cannot predict the likelihood, nature, or extent of healthcare reform initiatives that may arise from future legislation or administrative action, particularly as a result of the recent presidential election.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates and any future product candidates we develop, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration 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 biologic is eligible for the extension 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 patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life

beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. 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 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. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

U.S. regulation of companion diagnostics

Our product candidates may require use of an *in vitro* diagnostic to identify appropriate patient populations. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, companion diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval.

If use of companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "*In Vitro* Companion Diagnostic Devices." According to the guidance, for novel candidates such as our product candidates, a companion diagnostic device and its corresponding drug or biologic candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a biologic product candidate generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. In July 2016, the FDA issued a draft guidance document intended to further assist sponsors of therapeutic products and sponsors of *in vitro* companion diagnostic devices on issues related to co-development of these products.

The FDA generally requires companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic contemporaneously with approval of the therapeutic. The review of these *in*

vitro companion diagnostics in conjunction with the review of therapeutic candidates involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are also subject to an application fee.

PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. In addition, as part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or a not-approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will issue an order denying approval of the PMA or issue a not approvable order. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

European Union Drug Development

In the European Union, or EU, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU member states have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 28 member states of the EU and Iceland, Liechtenstein, Norway, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a member state of the EEA, this National MA can be recognized in other member states through the Mutual Recognition Procedure. If the product has not received a National MA in any member state at the time of application, it can be approved simultaneously in various member state through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the member state in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other member state, referred to as the Member States Concerned, for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the member states (i.e., in the RMS and the Member States Concerned). Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

European Union Orphan Designation and Exclusivity

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for MA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

European Union Drug Marketing

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

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

European Data Collection

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive, and as of May 2018 the General Data Protection Regulation, or GDPR. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the EU member states may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Reimbursement

Sales of our products, when and if approved, will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, coverage determination is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of biosimilars for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a

pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and reimbursement. Obtaining coverage and reimbursement for newly approved drugs and biologics is a time-consuming and costly process, and coverage may be more limited than the purposes for which a drug is approved by the FDA or comparable foreign regulatory authorities. Assuming coverage is obtained 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. Additionally, coverage policies and third-party reimbursement rates may change at any time. 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 their prescription drugs. Patients are unlikely to use products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of prescribed products.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Employees and Human Capital Resources

As of March 15, 2021, we had 30 full-time employees and 2 part-time employees. 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 new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

Our common stock is listed on The Nasdaq Global Market under the symbol "SNSE".

Our principal executive offices are located at 1405 Research Blvd, Suite 125, Rockville, MD 20850. Our telephone number is (240) 243-8000.

The Sensei design logo, "Sensei", "ImmunoPhage", "Phortress" and our other registered or common law trademarks, service marks, or trade names appearing in this Annual Report on Form 10-K are the property of Sensei Biotherapeutics, Inc. Other trade names, trademarks and service marks used in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K exclude the ® or TM symbols.

Available Information

Our website address is www.senseibio.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act are made available

free of charge on or through our website as soon as reasonably practicable after such reports are filed with, or furnished to, the United States Securities and Exchange Commission, or SEC. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Report on Form 10-K. The occurrence of Any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- ***Risks Related to our Financial Position***
  - We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
  - We will need additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
  - Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business.
- ***Risks Related to the Development of our Product Candidates***
  - Our development efforts are in the early stages. All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
  - The development of product candidates with our ImmunoPhage platform represents an emerging approach to the treatment of cancer and infectious diseases and faces significant challenges and hurdles. We may not be successful in applying our ImmunoPhage platform to the discovery and development of commercially viable products.
  - Our business is highly dependent on the success of our lead product candidate, SNS-301 and any other product candidates that we advance into the clinic. All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially. If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
  - Interim data from our clinical trials that we announce or publish from time to time, such as the data from our Phase 1/2 clinical trial of SNS-301 for the treatment of SCCHN, may change as more patients are enrolled and additional data become available.
  - We depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
  - Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.
- ***Risks Related to our Dependence on Third Parties***
  - We collaborate with third parties in connection with the development of our product candidates, and may depend upon future collaboration partners to commit to the research, development, manufacturing and marketing of our product candidates.

- We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

- ***Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters***
  - Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.
- ***Risks Related to the Commercialization of our Product Candidates***
  - If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.
  - We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
  - Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- ***Risks Related to our Intellectual Property***
  - If we are unable to obtain and maintain patent protection for our ImmunoPhage platform and phase-based cocktail technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
  - Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.
- ***Risks Related to our Business Operations***
  - We will need to grow the size of our organization, and we may experience difficulties in managing this growth.
  - Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.
- ***Risks Related to our Securities and our Status as a Public Company***
  - The trading price of our common stock may be volatile, and you could lose all or part of your investment.
  - If we fail to implement and maintain an effective system of internal control over financial reporting to remediate our material weaknesses, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of our common stock may be materially and adversely affected.

Risks Related to Our Financial Position

We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage immunotherapy company and we have incurred significant net losses since our inception. Our net loss was $20.1 million and $16.7 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $112.4 million. We have funded our operations to date primarily with proceeds from the sale of our equity securities and borrowings of convertible debt.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to research and development of our ImmunoPhage platform and SNS-301, and to our other product candidates. Investment in therapeutic product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable.

We expect that it will take at least several years until any of our product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will

adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- complete our Phase 1/2 clinical trial of SNS-301 and continue clinical development of SNS-301;
- prepare to file INDs and then initiate clinical development of additional product candidates, including SNS-401 and SNS-VISTA;
- continue the research and development of our other product candidates;
- invest in our ImmunoPhage platform;
- seek to discover and develop additional product candidates or acquire or in-license drugs, product candidates or technologies;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- manufacture our product candidates or otherwise secure the clinical and commercial supply of our product candidates;
- hire additional research and development and selling, general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional costs associated with operating as a newly public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Achievement will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete late-stage clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer. In addition, we will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We will need additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We will require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our product development programs or commercialization efforts.

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

- the scope, progress, results and costs of discovery, laboratory testing, manufacturing, preclinical and clinical development for our current and future product candidates;
- the development requirements of other product candidates that we may pursue;
- the timing and amounts of any milestone or royalty payments we may be required to make or may be entitled to receive under license agreements;
- the costs of building out our infrastructure including hiring additional clinical, quality control and manufacturing personnel;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

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

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

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 stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. 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 or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our common stock to decline.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Risks Related to the Development of our Product Candidates

Our development efforts are in the early stages. All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our lead product candidate, SNS-301, is our only product candidate in clinical development. There is no assurance that this, or any other future clinical trials of our product candidates, will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any of our product candidates. With the exception of SNS-301, we have not submitted an IND to the FDA. Our other product candidates are in preclinical development. There can be no assurance that the FDA will permit the INDs for our other product candidates to go into effect in a timely manner or at all. Without the IND, we will not be permitted to conduct clinical trials in the United States.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- completing preclinical studies;
- submission of INDs for and receipt of allowance to proceed with our planned clinical trials or other future clinical trials;
- initiating, enrolling, and completing clinical trials;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidates;
- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors; manufacturing our product candidates at an acceptable cost; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our products and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which would materially harm our business.

The development of product candidates with our ImmunoPhage platform represents an emerging approach to cancer treatment and faces significant challenges and hurdles. We may not be successful in applying our ImmunoPhage platform to the discovery and development of commercially viable products.

We have concentrated our primary research and development efforts on our ImmunoPhage platform which utilizes the power of bacteriophage to facilitate the creation of vaccines for enhanced immune system activation. Our future success is highly dependent on the successful development and manufacture of our product candidates. We do not currently have any approved or commercialized products. Because bacteriophage-based therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- obtaining regulatory approval for our product candidates, as the FDA and other regulatory authorities have limited experience with phage-based therapies for cancer;
- patients receiving chemotherapy in conjunction with the delivery of our product candidates, which may increase the risk of adverse side effects of our product candidates;
- sourcing clinical and, if approved, commercial supplies of the materials used to manufacture our product candidates;
- developing product candidates with desired properties, while avoiding adverse reactions;
- establishing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements;
- achieving cost efficiencies in the scale-up of our manufacturing capacity;

- developing protocols for the safe administration of our product candidates;
- educating medical personnel regarding our phage-based technologies and the potential side effect profile of each of our product candidates; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our phage-based product candidates or any other product candidates in a manner that will yield products that are safe and effective, scalable or profitable.

Moreover, physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of our therapies. Based on these and other factors, health systems, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our SNS-301 product candidate and our preclinical programs. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies, that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA and other regulatory authorities regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA and other regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other comparable regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials, including with respect to our ImmunoPhage cocktail approach;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application, or BLA, or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or our facilities;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

Many of these risks are beyond our control, including the risks related to clinical development. If we are unable to develop, receive regulatory approval for, or successfully commercialize SNS-301 or our other product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our business is highly dependent on the success of our lead product candidate, SNS-301 and any other product candidates that we advance into the clinic. All of our product candidates may require significant additional preclinical and clinical development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is utilizing our ImmunoPhage platform to develop what we believe are safer and more effective and personalized phage-based vaccines. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are very early in our development efforts, and our product candidates, including SNS-301, are in early clinical development. Because SNS-301 is our lead product candidate, if SNS-301 encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed. By leveraging insights gained from our experience with SNS-301, we have adapted our platform to generate personalized, off-the-shelf product candidates based on a cocktail of common and patient-specific antigens, dosed together as an array of customized, multi-antigen phage configurations in a modular approach. However, we may not be able to develop product candidates that are safe and effective, or which compare favorably with other commercially available alternatives. Even if we are successful in continuing to build our pipeline and develop personalized, off-the-shelf product candidates, the potential product candidates that we identify may not be suitable for clinical development, including as a result of lack of safety, lack of tolerability, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. We cannot provide you with any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our ImmunoPhage platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

We are developing product candidates designed to produce responses against novel targets through a cocktail therapy approach for which there is little clinical experience, and the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to predict or provide clinically meaningful results.

SNS-301 has been engineered to produce a targeted immune response against ASPH. We are also developing a human mAb program targeting the novel immune checkpoint VISTA. There are currently no approved therapies that target ASPH or VISTA in the field of oncology. To evaluate these product candidates, we are also pioneering an adaptive clinical trial design that enables substitution of ImmunoPhage cocktail components throughout clinical development. As a result of the novelty of our targets as well as the novelty of our anticipated clinical trial design, the design and conduct of clinical trials of our product candidates or any future product candidate may take longer, be more costly or be less effective. There may also be inconsistent or contradictory efficacy or safety results amongst different cocktail product candidates for different patients in the same clinical trial. In some cases, we may use endpoints or methodologies that regulatory authorities may not consider to be clinically meaningful and that we may not continue to use in clinical trials or that we may determine after the initiation of the trial to no longer be an appropriate endpoint or methodology. Any such regulatory authority may require evaluation of additional or different clinical endpoints in our clinical trials or ultimately determine that these clinical endpoints do not support marketing approval. In addition, if we are required to use additional or different clinical endpoints by regulatory authorities, our product candidates may not achieve or meet such clinical endpoints in our clinical trials. Even if a regulatory authority finds our clinical trial success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we may conduct for our product candidate. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of other efficacy endpoints in the trial. Regulatory authorities also weigh the benefits of a product against its risks and may not view the efficacy and safety results we product with our adaptive clinical trial design as supportive of approval.

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 have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. 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 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.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Most of our product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. It is impossible to predict accurately when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA or regulatory authorities in other countries or jurisdiction to approve our BLA or other comparable application, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

It is impossible to predict when or if any of our current or future product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Human clinical trials are expensive, can take many years to complete, and are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for oncology product candidates proceeding through clinical trials, which may be higher for our product candidates because they are based on a new approach. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Success in preclinical studies or clinical trials may not be predictive of results in future clinical trials.

Results from preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials are not necessarily predictive of final results. While we have received initial data in our Phase 1/2 clinical trial of SNS-301 for the treatment of locally advanced unresectable or metastatic SCCHN, we still need to conduct additional clinical trials prior to seeking regulatory approval. We have also not yet begun clinical trials for our other product candidates. For that reason, we do not know whether these candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results observed in preclinical studies or having successfully advanced through initial clinical trials. This failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

Additionally, some of our past, planned and ongoing clinical trials utilize an open-label study design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved therapy or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that our Phase 1/2 clinical trial of SNS-301 includes an open-label dosing design, the results from this clinical trial may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional 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 publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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 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. Preliminary or 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 and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. For instance, we have reported interim data from our ongoing Phase 1/2 clinical trial of SNS-301 for the treatment of SCCHN based on our first 11 enrolled patients, of which ten patients were evaluable for efficacy as of December 10, 2020, and the overall results from the Phase 1/2 trial may materially change as we complete enrollment and report results for the full 30 patients that we anticipate enrolling in the trial. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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 potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

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 may be harmed, which could harm our business, operating results, prospects or financial condition.

We depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. 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. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- 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 or drugs that may be used off-label for these indications;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment; and
- factors we may not be able to control, such as current or potential pandemics, including the COVID-19 pandemic, that may limit patients, principal investigators or staff or clinical site available.

In particular, some of our clinical trials will look to enroll patients with specific limited characteristics. For instance, in our ongoing Phase 1/2 of SNS-301 in SCCHN, we restricted enrollment to SCCHN patients who were treated with PD1 blockade for at least 12 weeks and did not achieve an objective response or confirmed progression, which limits the pool of patients from which we have to recruit trial participants. In addition, because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than enroll patients in our clinical trials.

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 clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may seek Fast Track designation for some or all of our current or future product candidates, but we may be unable to obtain such designations or, where obtained, we may be unable to maintain such designations or obtain or maintain the benefits associated with such designations.

We may seek Fast Track designation for some or all of our other current and future product candidates, but we may be unable to obtain such designation or, where obtained, we may be unable to maintain such designation or obtain or maintain the benefits associated with such designation.

If a biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for SNS-301 and some or all of our other current and future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast

Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and, therefore, may be small, and our projections regarding the size of the addressable market may be incorrect.

Our immunotherapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancers are detected they are treated with first line of therapy with the intention of curing the cancer. This treatment generally consists of chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. If the patient's cancer relapses, then the patient is given a second line or third line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy is to control the growth of the tumor and extend the life of the patient, as a cure is unlikely to happen. Patients are generally referred to clinical trials in these situations.

While we are initially developing SNS-301 as a first line therapy and later lines of therapy for patients with SCCHN, there is no guarantee that it, or any of our product candidates, even if approved, would be approved for an early line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenues without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

We are developing SNS-301, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We are developing SNS-301, and may develop future product candidates, for use in combination with one or more currently approved cancer therapies. In particular, we are developing SNS-301 in combination pembrolizumab, an approved anti-PD-1 cancer treatment. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

If the FDA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with SNS-301 or any product candidate we develop, we may be unable to obtain approval of or market SNS-301 or any product candidate we develop.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.

Our clinical trials include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of our other product candidates will include similar patients with deteriorating health. It is possible that some of these patients may experience similar side effects and that additional patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate.

Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our therapeutic candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may decide to remove such products from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

We may not be successful in achieving cost of goods at commercial scale that provide for an attractive margin.

We have limited commercial manufacturing experience and may underestimate the cost and time required to establish manufacturing capacity at commercial scale, or overestimate cost reductions from economies of scale that can be realized with manufacturing processes. While we are planning to internally develop this capability, including plans for the potential construction of our own manufacturing facility, we have also held discussions with multiple contract manufacturing organizations regarding commercial-stage manufacturing. We may ultimately be unable to manage the cost of goods for our product candidates to levels that will allow for a margin in line with our expectations and return on investment if those product candidates are commercialized.

We may not be successful in manufacturing our product candidates on our own for use in clinical trials and, if approved, for commercial sale.

As we advance into later-stage clinical trials and additional indications, we intend to expand our current manufacturing capabilities to support larger scale clinical trials and the potential commercialization of our product candidates. However, we have not yet constructed or acquired manufacturing facilities or capabilities that would allow us to meet commercial-scale quantities.

The implementation of this plan is subject to many risks. For example, the expansion of a manufacturing facility is a complex endeavor requiring knowledgeable individuals. Expanding our internal manufacturing infrastructure will rely upon finding personnel with an appropriate background and training to staff and operate the facility. Should we be unable to find these individuals, we may need to rely on external contractors or train additional personnel to fill the needed roles. There are a small number of individuals with relevant experience and the competition for these individuals is high.

We may never be successful in expanding our own manufacturing capability to support large scale clinical trials and commercialization of product candidates, if approved. We may establish additional manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing operations could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce our product candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we 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 stopped.

We have developed a process for manufacturing and stock storing bacteriophage viruses and we believe that our current processes are readily scalable and suitable for commercialization. Each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. We have not yet manufactured or processed our product candidates on a commercial scale and may not be able to do so for any of our product candidates.

We may encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems include delays or break-downs in logistics and shipping, difficulties with production costs and yields, quality control, and product testing, operator error, lack of availability of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations.

Furthermore, if microbial, viral or other contaminations are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any of these or other issues relating to the manufacture of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Manufacturing facilities also require commissioning and validation activities to demonstrate that they operate as designed, and are subject to government inspections by the FDA and other comparable regulatory authorities. If we are unable to reliably produce products to specifications acceptable to the regulatory authorities, we may not obtain or maintain the approvals we need to manufacture our products. Further, manufacturing facilities may fail to pass government inspections prior to or after the commercial launch of our product candidates, which would cause significant delays and additional costs required to remediate any deficiencies identified by the regulatory authorities. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Prior treatments can alter the cancer and negatively impact chances for achieving clinical activity with our ImmunoPhage product candidates.

Patients with head and neck and other cancers typically receive highly toxic lympho-depleting chemotherapy as their initial treatments that can impact the patient's responses to new therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended ImmunoPhage and thereby lead to a selection of cancer cells with low or no expression of the target. As a result, our product candidates may not recognize the cancer cell and may fail to achieve clinical activity. If any of our product candidates do not achieve a sufficient level of clinical activity, we may discontinue the development of that product candidate, which could have an adverse effect on the value of our common stock.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of SNS-301 as well as for any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations, or CROs, or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, efficacy and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be

effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Risks Related to our Dependence on Third Parties

We collaborate with third parties in connection with the development of our product candidates, and may depend upon future collaboration partners to commit to the research, development, manufacturing and marketing of our product candidates.

We collaborate with third parties for the development of our product candidates, including, for instance, our clinical trial collaboration with AstraZeneca for future Phase 2 clinical trials of SNS-301 in combination with durvalumab in the neoadjuvant setting and our collaboration with the University of Washington pursuant to which we are conducting preclinical studies for our SNS-401 program. We may enter into additional collaborations for our other current or future product candidates or technologies. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development, manufacturing or marketing of our products. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons.

In order to optimize the launch and market penetration of certain of our future product candidates, we may enter into distribution and marketing agreements with pharmaceutical industry leaders. For these product candidates, we would not market our products alone once they have obtained marketing authorization. The risks inherent in entry into these contracts are as follows:

- the negotiation and execution of these agreements is a long process that may not result in an agreement being signed or that can delay the development or commercialization of the product candidate concerned;
- these agreements are subject to cancellation or non-renewal by our collaborators, or may not be fully complied with by our collaborators;
- in the case of a license granted by us, we lose control of the development of the product candidate licensed; in such cases, we would only have limited control over the means and resources allocated by our partner for the commercialization of our product; and
- collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

Should any of these risks materialize, or should we fail to find suitable collaborators, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

We have entered, and may in the future enter into, partnership agreements with third parties for the development and commercialization of our product candidates. Our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential

commercialization. As such, we have entered into and may seek to enter into additional collaborations or partnerships with third parties for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Should we seek to collaborate with a third party with respect to a prospective development program, we may not be able to locate a suitable partner or to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing partners for the development and commercialization of our product candidates, we have limited control over the time and resources that our partners may dedicate to the development and commercialization of our product candidates. These partnerships pose a number of risks, including the following:

- partners may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources or a change in strategic focus;
- partners may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- partners may decide to pursue a competitive product developed outside of the collaboration arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- partners may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, partnership agreements may not lead to development, regulatory approval or successful commercialization of product candidates in the most efficient manner or at all. Some partnership agreements are terminable without cause on short notice. Once a partnership agreement is signed, it may not lead to regulatory approval and commercialization of a product candidate. We also face competition in seeking out partners. If we are unable to secure new collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues.

We rely, and expect to continue to rely, on third parties to conduct the preclinical and clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical studies and clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good laboratory practices, or GLP, and good clinical practices, or GCP, for conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database within specified timeframes. Failure to do so by us or third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

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 product candidates.

In addition, principal 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 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 by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidates or any future product candidates.

To develop immunotherapeutic candidates, we rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for access to facilities and supply of certain materials and equipment used in the manufacture of our product candidates. For example, we purchase equipment and reagents critical for the manufacture of our product candidates from third parties on a purchase order basis. Some of our suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers, and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we may in the future rely on sole source vendors or a limited number of vendors. An inability to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, widespread business interruption, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

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

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. 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. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, 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. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. Whether the results from our current ongoing clinical trials and other trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more controlled clinical trials to obtain approval. Additionally, even if FDA does grant approval for one or more of our product candidates, it may be for a more narrow indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop.

We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted BLA, premarket approval application, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our preclinical studies or clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. 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 studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail 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. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;

- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA'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. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

If we are unable to successfully validate, develop and obtain regulatory approval for any required companion diagnostic tests for our product candidates or experience significant delays in doing so, we may fail to obtain approval or may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may develop or engage third parties to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive benefit from our product candidates, as we are targeting certain genetically defined populations for our treatments. Such companion diagnostics may be used during our clinical trials and may be required in connection with the FDA approval of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. Companion diagnostics are subject to regulation by the FDA, EMA and other regulatory authorities as medical devices and require separate regulatory approval prior to commercialization.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. We and our future collaborators may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics. We and our future collaborators also may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval or such approval may be delayed, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue developing, selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic product candidates.

Our relationships with customers, healthcare professionals, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our current and future business operations and activities may subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our product candidates for which we obtain marketing approval. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other

business arrangements generally. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims, including the federal False Claims Act, or FCA, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the FCA;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act” under the Affordable Care Act, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, applicable manufacturers will be required to report information regarding payments and other transfers of value made to certain non-physician providers such as physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be 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, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and

commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. 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 current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) 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.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed several Executive Orders and other directives designed to eliminate the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation to date, the Tax Act, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear how the Supreme Court will rule. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act of 2011 have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012 among other things, reduced Medicare payments to several 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.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state 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 sought to implement several of the administration's proposals. As a result, the FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under 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 safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new U.S. presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business in light of the higher proportion of SCD patients that utilize Medicare and Medicaid programs to pay for treatments.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

We are subject to the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act, or FCPA, violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. 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, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. 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, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

We currently plan to work to build our global commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. To achieve commercial

success for any product candidate for which we may obtain marketing approval, we will need to expand our sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

In addition to the current standard of care treatments for patients with infectious diseases or cancers, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immunotherapy. Results from these studies and trials have fueled increasing levels of interest in the field of immunotherapy.

Large pharmaceutical companies that have commercialized or are developing immunotherapies to treat cancer include AstraZeneca, Bristol Myers Squibb, Gilead Sciences, Merck, Novartis, Pfizer, and Roche/Genentech.

On the technology level, other companies which can potentially develop competing product candidates which act to stimulate the body’s immune response as a treatment for SCCHN and other solid tumors include companies developing cell-based therapeutics such as CAR-T/TCR/NK therapies as well as companies developing therapeutic vaccines including BioNTech, Moderna, Gritstone Oncology and Oncorus, among others. In addition, a number of companies are developing oncolytic virus approaches, including Boehringer Ingelheim, Johnson and Johnson, Regeneron, Vyriad, Replimune and Turnstone. Amgen has received FDA approval for its oncolytic virus-based product, T-VEC.

Ablynx, a subsidiary of Sanofi, and Oncorus are actively pursuing the development of nanobodies as therapeutics.

Our competitors with development-stage programs may obtain marketing approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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 or better reimbursed than any products that we may commercialize. 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 for either the product or a specific indication before we are able to enter the market.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our clinical-stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective, may limit market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our product candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health

administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently do not have product liability in place as the cost of coverage exceeds the covered amount during clinical trials. Once we are ready for a product launch, we intend to bind a policy with product liability insurance coverage in the aggregate and a per incident limit at an amount adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, 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, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those 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 product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials, which has since been further updated. As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 16, 2020, FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, FDA may not be able to continue its current pace and review timelines could be extended. As of July 2020, utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, the FDA is either continuing to, on a case-by-case basis, conduct only mission critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. The FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace, and delays or setbacks are possible in the future. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. Additionally, 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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our phage-based vaccine and ASPH-targeting technologies and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States, Canada, China, the European Union and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications related to our technology and product candidates in the major pharmaceutical markets, including the United States, Canada, China, major countries in Europe and Japan. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary positions, we file patent applications in the United States and other countries related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could threaten our ability to commercialize our product candidates. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and 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 be certain that 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. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the

patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate 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.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary phage-based vaccine technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of biotechnology, including in the area of vaccine therapies and including patents held by our competitors. If any third-party patents cover our product candidates or technologies, we may not be free to manufacture or commercialize our product candidates as planned.

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 technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights and claims may also come from competitors against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future product candidates, competitors may claim that our technology infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization. There are and may in the future be additional third-party patents or patent applications with claims to, for example, materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of any one or more of our product candidates. Moreover, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that the claims of an issued patent are invalid or are not infringed by our activities. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our product candidates may infringe, or which such third parties claim are infringed by our 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 or may choose 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. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of

infringement or misappropriation is time-consuming, expensive and diverts the attention of our management from our ongoing business operations.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

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

Competitors may infringe our patents, if issued, trademarks, copyrights 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. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a 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 patents do not cover the invention. 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. 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.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance 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. 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. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

We may be subject to claims challenging the inventorship or ownership of our owned patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any 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. Furthermore, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, 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 lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and patent agencies outside the United States in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse 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 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 products or product candidates, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

Risks Related to our Business Operations

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 15, 2021, we had 32 employees, 30 of whom are employed full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel to support our product development and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the preclinical, clinical and FDA review processes for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in immunotherapy and the competition for these individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to

effectively manage any future growth, and our management may also have to divert 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, 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.

In addition to expanding our organization, we anticipate increasing the size of our facilities and building out our development and manufacturing capabilities, which would require significant capital expenditures. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the increase in the size of our facilities is delayed, it may limit our ability to rapidly expand the size of our organization in order to meet our corporate goals.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. We are highly dependent on our management, scientific and medical personnel, including John Celebi, our Chief Executive Officer, Dr. Marie-Louise Fjaellskog, our Chief Medical Officer, Dr. Robert Pierce, our Chief Scientific Officer, and Anupama Hoey, our Chief Business Officer. Our senior management may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. 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. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. For instance, in May 2020, we acquired Alvaxa Biosciences LLC to enhance the depth of our nanobody assets and know-how. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to our Securities and our Status as a Public Company

An active trading market for our common stock may not continue to develop or be sustained.

Prior to our initial public offering, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all.

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical 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, investors may not be able to sell their common stock at or above the price paid for the common stock. In addition to the factors discussed elsewhere in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure and scope of health care payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates or ImmunoPhage platform in general;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on Nasdaq;
- sales of our common stock by us, members of our senior management and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common stock at or above the price paid for the common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. From time to time, we have been, and may continue to be, subject to legal proceedings and claims in the ordinary course of business. For instance, during 2017, we became actively involved, along with other defendants, in a breach of contract claim in the Ontario (Canada) Superior Court of Justice seeking declaratory and other relief, including monetary damages. While we believe there is no merit to the allegations of that claim, any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

The shares sold in our initial public offering are freely tradable, and the remaining 22,558,200 shares of common stock will be available for sale in the public market beginning 180 days after the date of pricing our initial public offering, or with respect to shares purchased in our Series BB financing, 120 days after the date of pricing our initial public offering, following the expiration of lock-up agreements entered into by our stockholders in connection with the offering and subject to the restrictions of Rule 144 of the Securities Act. The representatives of the underwriters may agree to release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of restrictions in the lock-up agreements, could cause the market price of our common stock to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

In addition, we have filed a registration statement registering the issuance of approximately 7.3 million shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, the holders of an aggregate of approximately 19.0 million of our shares of common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

If we fail to implement and maintain an effective system of internal control over financial reporting to remediate our material weaknesses, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of our common stock may be materially and adversely affected.

Prior to our initial public offering, we only had limited accounting personnel and other resources with which to address internal control over financial reporting. In connection with the audits of our consolidated financial statements as of and for the years ended December 31, 2019 and 2020, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, or PCAOB, a "material weakness" is a deficiency, or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We are in the process of implementing a number of measures to address the material weaknesses and deficiencies that have been identified including: (i) hiring additional accounting and financial reporting personnel with generally accepted accounting principles in the United States, or US GAAP, and SEC reporting experience, (ii) developing, communicating and implementing an accounting policy manual for our accounting and financial reporting personnel for recurring transactions and period-end closing processes, and (iii) establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our company's consolidated financial statements and related disclosures. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Internal Control Over Financial Reporting." However, we cannot assure

you that these measures may fully address the material weaknesses and deficiencies in our internal control over financial reporting or that we may conclude that they have been fully remediated.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting beginning with our second annual report on Form 10-K after becoming a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. In addition, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. Generally speaking, if we fail to achieve and maintain an effective internal control over financial reporting, it could result in material misstatements in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. As a result, our businesses, financial condition, results of operations and prospects, as well as the trading price of our common stock, may be materially and adversely affected. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, NOLs arising in taxable years beginning after December 31, 2017, and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss, and NOLs arising in tax years beginning after December 31, 2020 may not be carried back. Moreover, under the Tax Act as modified by the CARES Act, NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. The extent to which state income tax law will conform to the Tax Act and CARES Act is uncertain. As of December 31, 2020, we had NOL carryforwards for federal and state income tax purposes of approximately $81.3 million and $80.0 million, respectively. NOL carryforwards generated in 2020 and 2019 for federal tax reporting purposes of $16.6 million and $10.7 million, respectfully, have an indefinite life.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have not determined whether our NOLs are limited under Section 382 of the Code. We may have experienced an ownership change in the past, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, our ability to utilize NOLs of companies that we have acquired or may acquire in the future may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

We have begun to incur significantly increased costs as a result of operating as a company whose common stock is publicly traded, and our management will be required to devote substantial time to new compliance initiatives.

As a newly public company, we have begun to incur significant legal, accounting and other expenses that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting beginning with our second annual report on Form 10-K after becoming a public company. However, while we remain an emerging growth company or a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an emerging growth company, we are able to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our shares of common stock, held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter before that time, in which case we would no longer be an emerging growth company as of the following December 31st (the last day of our fiscal year). We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stockless attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum 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, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America, will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws;
- any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers or other employees that is governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Securities Exchange Act of 1934, or the Exchange Act, or any claim for which the U.S. federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation will provide 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.

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 any other court of competent jurisdiction were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

General Risk Factors

Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries worldwide, including the United States. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government ordered the closure of all non-essential businesses, imposed social distancing measures, "shelter-in-place" orders and restrictions on travel between the United States, Europe and certain other countries. The global pandemic and government measures taken in response have also had a significant impact on businesses and commerce worldwide, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended across a variety of industries; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. On March 18, 2020, the FDA issued updated industry guidance for conducting clinical trials during the COVID-19 pandemic, which requires clinical trial sponsors to consider the need to delay or cease patient recruitment, change protocol regarding patient monitoring and assessment that minimizes in-person visits, alternative administration of certain investigational products due to compromised clinical sites and to put in place new processes or modify existing processes in consultation with the FDA that would ensure the safety of clinical trial participants. In connection with COVID-19, we implemented optional work-from-home policies for most employees. The effects of government orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires

management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic has resulted in significant disruption of global financial markets, resulting in an economic downturn that could continue to significantly impact our business and operations and may reduce our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. In addition, a recurrence or "second wave" of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest.

Further, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- 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 or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

These and similar, and perhaps more severe, disruptions in our operations could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we continue to monitor the COVID-19 situation closely. To the extent the COVID-19 pandemic adversely affects our business, results of operations, cash flows, financial condition and/or prospects, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants may be vulnerable to a variety of disruptive elements, including computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate

disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our product candidates could be delayed.

We are or may become subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain sensitive information, including confidential business and personal information in connection with our preclinical studies and our employees, and are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these constantly evolving laws can be subject to varying interpretations. In May 2018, a new privacy regime, the General Data Protection Regulation, the GDPR, took effect in the European Economic Area, the EEA, into which we may expand our business. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly.

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which took effect on January 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. 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 by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined and can include any of our current or future employees who may be California residents) and provide such residents new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. As we expand our operations and trials (both preclinical or clinical), the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States. Other states are beginning to pass similar laws.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to power shortages, telecommunications failures, water shortages, civil unrest, labor disputes, violence, earthquakes, floods, hurricanes, typhoons, fires, extreme weather conditions, infectious disease, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our common stock could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or

research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our principal executive offices are located in Rockville, Maryland, pursuant to a lease that expires in February 2027. We also lease office and laboratory space in Boston, Massachusetts, pursuant to a lease that expires in May 2026. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in other litigation or legal proceedings relating to claims arising from the ordinary course of business.

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.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

Stockholders

Our common stock is listed on the Nasdaq Global Market under the symbol "SNSE". As of March 25, 2021, we had 30,588,495 shares of common stock outstanding held by 327 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Use of Proceeds from Initial Public Offering of Common Stock

On February 3, 2021, our Registration Statement on Form S-1, as amended (File No. 333-252704) was declared effective in connection with our initial public offering, or IPO, pursuant to which we sold 8,030,295 shares of our common stock, including the partial exercise of the underwriters' option to purchase additional shares, at a price to the public of $19.00 per share. The initial closing of our initial public offering occurred on February 8, 2021. We received net proceeds from the initial public offering of $138.5 million (after deducting underwriters' discounts and commissions and additional offering related costs of $14.1 million). Citigroup, Piper Sandler & Co. and Berenberg acted as joint book-running managers for the IPO. Oppenheimer & Co. acted as the lead manager for the IPO.

No expenses incurred by us in connection with our initial public offering were paid directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from our initial public offering from those disclosed in the final prospectus for our initial public offering dated as of February 3, 2021 and filed with the SEC on February 4, 2021 pursuant to Rule 424(b)(4).

Recent Sales of Unregistered Securities

Preferred Stock

From December 2020 through the date hereof, we sold an aggregate of 165,956,208 shares of Series BB convertible preferred stock to a total of 43 accredited investors at a purchase price per share of $0.207383 per share for an aggregate gross proceeds of $34.4 million.

From January 2020 through the date hereof, we issued an aggregate of 747,683,172 shares of our Series AA convertible preferred stock to a total of 128 accredited investors at a price per share of $0.082135 per share. We received aggregate gross proceeds of $26.1 million for the sale of 317,608,273 shares of Series AA convertible preferred stock. The redemption of convertible notes resulted in the issuance of 219,764,874 shares of Series AA convertible preferred stock. In exchange for our convertible preferred stock series A through F, including cumulative and unpaid dividends, we issued 210,310,025 shares of Series AA convertible preferred stock as part of the Recapitalization.

On February 8, 2021, upon the closing of our initial public offering, all shares of our then-outstanding convertible preferred stock were automatically converted into 19,034,069 shares of common stock. The issuance of such shares of common stock was exempt from the registration under Section 3(a)(9) of the Securities Act.

Warrants to Purchase Common Stock

From January 1, 2020 through February 2, 2021, we issued warrants to purchase 2,748,243 shares of common stock to accredited investors, at exercise prices ranging from $0.01 to $3.95 per share. Of these, warrants to purchase an aggregate of 4,094 shares have been cancelled without being exercised and 2,358,918 shares have been issued upon the exercise of warrants, at a weighted average exercise price of $0.01 per share.

Option and Common Stock Issuances

From January 1, 2020 through February 2, 2021, we granted to certain employees, consultants and directors options to purchase an aggregate of 1,972,423 shares of common stock under our 2018 Plan, at exercise prices ranging from $1.23 to $9.22 per share. Of these, options to purchase an aggregate of 13,322 shares have been cancelled without being exercised and 16,666 shares have been issued upon the exercise of stock options, at a weighted average exercise price of $1.23 per share, for aggregate proceeds of approximately $20,400.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

Item 6. Selected Financial Data.

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage immunotherapy company engaged in the discovery and development of next-generation therapies with an initial focus on treatments for cancer. Our ImmunoPhage platform is a powerful, self-adjuvanted and highly differentiated immunotherapy approach that is designed to utilize bacteriophage to induce a robust, focused and coordinated innate and adaptive immune response. We are engineering our ImmunoPhage product candidates to directly target APCs and modulate the TME through the targeted use of nanobodies to further enhance therapeutic activity. We believe our ImmunoPhage platform has the potential to deliver on the promise of personalized, off-the-shelf product candidates tailored to a patient's specific tumor. The versatility of our ImmunoPhage platform allows us to design product candidates in a modular fashion, based on a cocktail of common and patient-specific antigens built from our proprietary library of ImmunoPhages, which we refer to as Phortress. We are currently conducting an ongoing 30-patient Phase 1/2 clinical trial of our lead product candidate, SNS-301, in combination with the PD-1 inhibitor pembrolizumab, as a potential treatment for SCCHN. As of March 9, 2021, we have enrolled 17 patients in the trial. As of December 10, 2020, we have evaluated ten patients for efficacy and ten for safety. We have observed disease control in seven of the patients evaluable for efficacy, including one patient with a PR, and two patients who have achieved longstanding SD for greater than 36 weeks following treatment. Treatment with SNS-301 has generally been well tolerated. We anticipate reporting a large additional subset of data from this trial by the end of 2021. If the results of this trial are positive, subject to feedback from the FDA, we intend to initiate a randomized, registration-enabling trial for SNS-301. We are leveraging the insights from our experience with SNS-301 to expand our development pipeline to include SNS-401 for the treatment of MCC and a human mAb program targeting the novel immune checkpoint VISTA.

Since our inception, we have devoted the majority of our efforts and financial resources to research and development activities related to our ImmunoPhage platform and our lead product candidate SNS-301, including raising capital, protecting our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any product candidates approved for sale, have not generated any revenue from product sales, and do not expect to generate any revenue from product sales for at least the next several years. We have largely funded our operations with proceeds from the sale of convertible preferred stock, common stock and convertible debt. Through the date of this report, we have raised an aggregate of $123.4 million of gross proceeds from private placements of our equity and convertible debt securities and net proceeds of $138.5 million from our initial public offering, or IPO, in February 2021.

We have incurred significant operating losses over the last several years. Our net loss was $20.1 million and $16.7 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $112.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- complete our Phase 1/2 clinical trial of SNS-301 and continue clinical development of SNS-301;
- prepare to file INDs and then initiate clinical development of additional product candidates, including SNS-401 and SNS-VISTA;
- continue the research and development of our other product candidates;
- invest in our ImmunoPhage platform;
- seek to discover and develop additional product candidates or acquire or in-license drugs, product candidates or technologies;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- manufacture our product candidates or otherwise secure the clinical and commercial supply of our product candidates;
- hire additional research and development and selling, general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio; and

- incur additional costs associated with operating as a public company.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses and negative cash flows for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product.

Recapitalization and Recent Security Issuances

In January 2020, we entered into an agreement with a third party, who is the holder of the 2019 Bridge Note with a principal balance of $1.0 million, and the holders of a majority of our Series A through F convertible preferred stock, or the Majority Legacy Preferred Stockholders, that provided a new source of capital and restructured our existing capital structure, or the Recapitalization. The third party invested $4 million in exchange for 48,700,311 shares of Series AA convertible preferred stock, or our Series AA Preferred Stock, and a warrant to purchase 634,118 shares of our common stock at an exercise price of $0.01 per share. The warrant was subsequently exercised in January 2020. Additionally, the agreement with the Majority Legacy Preferred Stockholders caused all other holders of our Series A through F convertible preferred stock, or the Minority Legacy Preferred Stockholders, and the Majority Legacy Preferred Stockholders to receive an aggregate of 627,871 shares of our common stock, or the Newly Issued Common Stock, in exchange for their holdings of our Series A through F convertible preferred stock, including cumulative and unpaid dividends, as part of the Recapitalization.

The Majority Legacy Preferred Stockholders agreed to invest additional capital in exchange for Series AA Preferred Stock. The Minority Legacy Preferred Stockholders were provided the opportunity to invest additional capital in exchange for Series AA Preferred Stock. All Majority and Minority Legacy Preferred Stockholders who invested additional capital during January 2020 were allowed to convert their Newly Issued Common Stock into Series AA Preferred Stock at a conversion rate based upon their incremental and historical investment. The Majority and Minority Legacy Preferred Stockholders invested $6.6 million in exchange for 79,954,952 shares of Series AA Preferred Stock. The Majority and Minority Legacy Preferred Stockholders also exchanged 148,732 shares of Newly Issued Common Stock for 210,310,025 shares of Series AA Preferred Stock under the Recapitalization agreement.

Our issuance of Series AA Preferred Stock triggered the redemption of certain convertible promissory notes, as well as accrued and unpaid interest and repayment premium, as applicable for certain notes, into shares of Series AA Preferred Stock. These debt instruments were redeemed for 188,173,050 shares of the Series AA Preferred Stock, which resulted in a gain on debt extinguishment of $45 thousand. Our remaining convertible promissory note was redeemed in November 2020.

On May 7, 2020, we issued warrants to a third party to purchase 389,325 shares of our common stock with an exercise price of $3.95 per common share. As of December 31, 2020, these warrants have not been exercised and have a five-year maturity date.

From October to November 2020, we issued and sold 85,499,239 shares of Series AA convertible preferred stock at $0.082135 per share in exchange for $7.0 million in gross proceeds.

From December 2020 through January 2021, we issued and sold 165,956,208 shares of our Series BB convertible preferred stock at a purchase price of $0.207383 per share for aggregate gross proceeds of $34.4 million.

In February 2021, we issued and sold an aggregate of 8,030,295 shares of our common stock at a price to the public of $19.00 per share for aggregate gross proceeds of $152.6 million in our initial public offering.

Impact of COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and to date, the COVID-19 pandemic continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and are difficult to predict. While we continue to conduct our research and development activities, the COVID-19 pandemic may cause disruptions that impact the timing of our ongoing and planned clinical trials of SNS-301 and affect our ability to complete preclinical studies, future clinical trials or to procure items that are essential for our research and development activities.

In addition, a recurrence or "second wave" of COVID-19 cases could cause other widespread or more severe impacts depending on where infection rates are highest. We plan to continue to closely monitor the ongoing impact of the COVID-19 pandemic on our employees and our business operations, as we deal with the disruptions and uncertainties relating to the COVID-19 pandemic. In an effort to provide a safe work environment for our employees, we have, among other things, implemented various social distancing measures in our office and labs including replacing in-person meetings with virtual interactions, and are working remotely when possible. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic. To date, there has not been a significant impact on the development of SNS-301 or the rest of our pipeline; however we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic could potentially have on our ongoing business plan, financial condition and operations.

Components of Our Results of Operations

Operating Expenses

Research and Development Expense

Our research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses include:

- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- the cost of manufacturing our product candidates including the potential cost of CMOs that manufacture product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- the cost of outsourced professional scientific development services;
- employee-related expenses, including salaries, benefits and stock-based compensation for employees engaged in the research and development function;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- fees for maintaining licenses and other amounts due under our third party licensing agreements;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We do not track our research and development expenses by program. Our direct external research and development expenses consist primarily of external costs, such as fees paid to CROs, CMOs, research/testing laboratories and outside consultants in connection with our preclinical development, process development, manufacturing and clinical development activities. We do not allocate these costs to specific product candidates because many of them are deployed across several of our development programs and, as such, are not separately classified. We use internal resources primarily to conduct research and manage our preclinical development, outsourced clinical trials, process development, manufacturing and clinical development activities. These employees work across multiple development programs and, therefore, we do not track their costs by program and, as such, are not separately classified. Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our registration-enabling clinical trial of SNS-301 in patients with SCCHN, conduct other clinical trials and prepare regulatory filings for our product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our other product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the scope, progress, outcome and costs of our preclinical studies and clinical trials of SNS-301, our other product candidates and any other product candidates we may acquire or develop;

- manufacturing of our product candidates or making arrangements with potential third-party manufacturers for both clinical and commercial supplies of these product candidates;
- successful patient enrollment in, and the initiation, duration and completion of clinical trials;
- the cost of gaining regulatory approvals for our product candidates, subject to the successful outcome of ongoing and future clinical trials; and
- the extent of any required post-marketing approval commitments to applicable regulatory authorities.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and significant additional development costs.

General and Administrative Expense

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for legal, auditing and tax services, and insurance costs.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with Nasdaq listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company.

Alvaxa IPR&D

On May 18, 2020, we acquired Alvaxa Biosciences, or Alvaxa, in a cash and stock purchase pursuant to a Stock Purchase Agreement. Under the terms of the Stock Purchase Agreement, we acquired Alvaxa's existing camelid nanobodies and other biomaterials, or the Biomaterials, expertise in nanobody discovery, as well as a license agreement with a research organization. The former majority shareholder of Alvaxa is our current Chief Scientific Officer. Under the Stock Purchase Agreement, we paid $197 thousand to settle liabilities assumed from Alvaxa and issued 304,376 shares of our common stock to the shareholders of Alvaxa. We have evaluated the acquisition under ASC 805, *Business Combinations* and determined this to be an asset acquisition.

The 304,376 shares of common stock was valued at $1.78 per share, or $541 thousand in total, based on a valuation determined with the assistance of a third party. We determined that substantially all the value acquired in the transaction related to the Biomaterials and represents in-process research and development, or IPR&D. The liabilities of $197 thousand assumed were related to previously incurred employee costs as well as contractually required vendor payments. The consideration transferred in this transaction was recorded as an expense in the IPR&D line item within our Statement of Operations during the year ended December 31, 2020.

Other Expense

Our other expense consists of changes in the fair value of our derivative liability related to an embedded derivative on certain 2019 promissory notes, gain/loss on debt extinguishments and interest expense on our outstanding convertible debt.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

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

(in thousands)	Year Ended December 31, 2020	2019	Change
Operating expenses:			
Research and development	$ 11,185	$ 8,350	$ 2,835
General and administrative	7,528	4,085	3,443
Alvaxa IPR&D	738	—	738
Total operating expenses	19,451	12,435	7,016
Loss from operations	(19,451)	(12,435)	(7,016)
Total other expense	(649)	(4,305)	3,656
Net loss	$ (20,100)	$ (16,740)	$ (3,360)

Research and Development Expenses

Research and development expenses were $11.2 million for the year ended December 31, 2020, compared to $8.4 million for the year ended December 31, 2019. The increase of $2.8 million was primarily attributable to investments being made in early research and development activities and the clinical and preclinical development of SNS-301, SNS-401 and SNS-VISTA.

General and Administrative Expenses

General and administrative expenses were $7.5 million for the year ended December 31, 2020, compared to $4.1 million for the year ended December 31, 2019. The increase of $3.4 million was primarily attributable to consulting fees for strategic and development-related advice, stock-based compensation expense resulting from new stock award grants during 2020, and additional recruiting fees incurred for the hiring of additional team resources.

Other Expense

Other expense was $0.6 million for the year ended December 31, 2020, compared to $4.3 million for the year ended December 31, 2019. The decrease of $3.7 million was primarily attributable to fair value adjustments of embedded derivative liabilities associated with certain 2019 promissory notes, as well as lower interest expense on debt due to the redemption of notes in 2020.

Comparison of Years Ended December 31, 2019 and 2018

The following sets forth our results of operations for the years ended December 31, 2019 and 2018:

(in thousands)	Year Ended December 31, 2019	2018	Change
Operating expenses:			
Research and development	$ 8,350	$ 8,227	$ 123
General and administrative	4,085	4,513	(428)
Total operating expenses	12,435	12,740	(305)
Loss from operations	(12,435)	(12,740)	305
Total other expense	(4,305)	(299)	(4,006)
Net loss	$ (16,740)	$ (13,039)	$(3,701)

Research and Development Expenses

Research and development expenses were $8.4 million for the year ended December 31, 2019, compared to $8.2 million for the year ended December 31, 2018. Costs remained relatively flat between the two years, with investments being made in early research and development activities and the clinical and preclinical development of SNS-301, SNS-401 and SNS-VISTA.

General and Administrative Expenses

General and administrative expenses were $4.1 million for the year ended December 31, 2019, compared to $4.5 million for the year ended December 31, 2018. The decrease of $0.4 million was primarily attributable to decreased spend associated with external corporate legal costs, partially offset by an increase headcount-related costs in the same period.

Other Expense

Other expense was $4.3 million for the year ended December 31, 2019, compared to $0.3 million for the year ended December 31, 2018. The increase of $4.0 million was primarily attributable to a $2.0 fair value adjustments of embedded debt derivative liability associated with certain 2019 promissory notes, and an increase of $2.0 million in interest expense on outstanding convertible promissory notes.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any product revenue and have incurred net losses and negative cash flows from our operations. We have financed our operations through sales of our common stock, convertible preferred stock and convertible debt. Through the date of this report, we have raised an aggregate of $123.4 million of gross proceeds from private placements of our equity and convertible debt securities and net proceeds of $138.5 million from our initial public offering, or IPO, in February 2021. Our net loss was $20.1 million and $16.7 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $112.4 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures.

As of December 31, 2020, we had cash and cash equivalents of $16.6 million. From December 2020 to January 2021, we issued and sold 165,956,208 shares of Series BB convertible preferred stock to a group of investors, in exchange for $34.4 million of new gross proceeds, of which approximately $10.9 million was received in December 2020. In February 2021, we issued an aggregate of 8,030,295 shares of common stock in our initial public offering at a price to the public of $19.00 per share, for aggregate gross proceeds of $152.6 million. We paid underwriting discounts and commissions of $10.7 million, and we also incurred expenses of $3.4 million in connection with the offering. As a result, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were $138.5 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods below:

	Year Ended December 31,	
(in thousands)	**2020**	**2019**
Net cash used in operating activities	$ (17,705)	$ (8,571)
Net cash used in investing activities	(1,403)	(53)
Net cash provided by financing activities	35,453	8,222
Net increase (decrease) in cash and cash equivalents	$ 16,345	$ (402)

Operating Activities

During the year ended December 31, 2020, our operating activities used $ 17.7 million of cash, primarily resulting from our net loss. During the year ended December 31, 2019, operating activities used $8.6 million of cash, primarily resulting from our net loss. The increase in net cash used in operating activities for the year ended December 31, 2020 as compared to the year ended December 31, 2019 is attributed to the increase in net loss.

Investing Activities

During the year ended December 31, 2020, net cash used in investing activities was $1.4 million from the purchase of Alvaxa and purchases of property and equipment. During the year ended December 31, 2019, net cash used in investing activities was related to purchases of property and equipment.

Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was $35.5 million, primarily from the issuance of our Series AA and Series BB convertible preferred stock, as well as $0.6 million received in unsecured loan funding from the Paycheck Protection Program, offset by approximately $2.1 million of IPO costs. During the year ended December 31, 2019, net cash provided by financing activities was $8.2 million from the issuance of convertible promissory notes, as well as cash proceeds from the exercise of common stock warrants.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and potentially seek marketing approval for, our product candidates. In addition, we expect to incur significant costs associated with operating as a newly public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of current and future preclinical studies and clinical trials for SNS-301, SNS-401 and SNS-VISTA and our other product candidates;
- the cost and timing of the manufacture of additional clinical trial material as well as any costs related to the scale-up of manufacturing activities;
- the costs to seek regulatory approvals for any product candidates that successfully complete clinical trials;
- the extent to which we or any third-party service providers on whom we rely experience delays or interruptions to preclinical studies and clinical trials, or to our supply chain due to the COVID-19 pandemic;
- the need to hire additional clinical, quality assurance, quality control and other scientific personnel;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting and maintaining compliance with regulatory requirements;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the terms of any collaboration agreements we may choose to enter into, including the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the cost associated with the expansion of our operational, financial and management systems and increased personnel, including personnel to support our operations as a public company; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products, if approved, on our own.

We expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements at least into the second half of 2023. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production;

- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- the impact of the COVID-19 pandemic and the corresponding responses of businesses and governments.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our 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 through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, 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.

Internal Control Over Financial Reporting

During the audit of our financial statements for the year ended December 31, 2020, material weaknesses were identified in our internal control over financial reporting. Under standards established by the PCAOB, a “material weakness” is a deficiency, or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We are in the process of implementing a number of measures to address the material weaknesses and deficiencies that have been identified including: (i) hiring additional accounting and financial reporting personnel with generally accepted accounting principles in the United States, or US GAAP, and SEC reporting experience, (ii) developing, communicating and implementing an accounting policy manual for our accounting and financial reporting personnel for recurring transactions and period-end closing processes, and (iii) establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our company’s consolidated financial statements and related disclosures.

These additional resources and procedures are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. With the oversight of senior management and our audit committee, we have begun taking steps and plan to take additional measures to remediate the underlying causes of the material weaknesses.

We intend to complete the implementation of our remediation plan during fiscal year 2021. Although we believe that our remediation plan will improve our internal control over financial reporting, additional time may be required to fully implement it and to make conclusions regarding the effectiveness of our internal control over financial reporting. Our management will closely monitor and modify, as appropriate, the remediation plan to eliminate the identified material weakness.

If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses.

We, and our independent registered public accounting firm, were not required to report on our evaluation of the Company’s internal control over financial reporting as of December 31, 2020 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the U.S. Securities and Exchange Commission.

Critical Accounting Policies and Significant Judgements and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which are prepared in accordance with US GAAP. The preparation of our financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in note 2 to our annual financial statements beginning on page F-1 of this Form 10-K, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Accrued Research and Development Expenses

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by CROs and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include, the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the consolidated statements of operations. We determine the estimated costs through discussions with the internal personnel and external service providers as to the progress, or stage of completion of the services and the agreed-upon fees to be paid for such services. This process involves a thorough review of open contracts and evaluation by internal personnel to identify services received that have been performed for us and estimating the associated cost incurred for these services for which we have not yet been invoiced or otherwise notified of the actual cost. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion of the services and the agreed-upon fees to be paid for such services. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Stock-Based Compensation

We measure all stock-based awards granted based on their estimated fair value on the date of the grant and recognize the corresponding compensation expense for those awarded to employees and directors over the requisite service period, which is generally the vesting period of the respective award, and for those awarded to nonemployees over the period during which services are rendered by nonemployees until completed. We have typically issued stock options and warrants with service-based vesting conditions and we record the expense for these awards using the straight-line method.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options and warrants, the risk-free interest rate for a period that approximates the expected term of our stock options and warrants and our expected dividend yield.

Recent Accounting Pronouncements

See note 2 in our annual financial statements included elsewhere in this Form 10-K for a description of recent accounting pronouncements applicable to our financial statements. Other than as disclosed in our financial statements, we do not expect that any recently issued accounting standards will have a material impact on our financial statements or will otherwise apply to our operations.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an EGC, as defined in the JOBS Act. As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an EGC earlier if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an EGC, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. We may choose to take advantage of some, but not all, of the available exemptions.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an EGC. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, refers to controls and procedures 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 such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our Chief Executive Officer and Senior Vice President of Finance and Administration, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on this evaluation, and due to the material weaknesses described elsewhere in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, the Chief Executive Officer and Senior Vice President of Finance and Administration concluded that, as of December 31, 2020, our disclosure controls and procedures were not effective.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2020 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

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

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth information for our executive officers and directors as of December 31, 2020:

Name	Age	Position
Executive Officers		
John Celebi	49	President, Chief Executive Officer and Director
Anupama Hoey	50	Chief Business Officer
Marie-Louise Fjaellskog, M.D., Ph.D.	56	Chief Medical Officer
Robert Pierce, M.D.	56	Chief Scientific Officer
Erin Colgan	40	Senior Vice President of Finance and Administration
Non-Employee Directors		
Bob Holmen(1)(2)	57	Director
James Peyer, Ph.D.(1)(3)	34	Director
Samuel Broder, M.D.(3)	75	Director
Thomas Ricks(1)(2)	67	Director
Deneen Vojta, M.D.(3)	56	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Governance Committee

Executive Officers

John Celebi has served as our President and Chief Executive Officer and a member of our board of directors since February 2018. Prior to joining us, from June 2016 until February 2018, Mr. Celebi served as Chief Operating Officer of X4 Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company. Prior to X4 Pharmaceuticals, from 2011 until June 2016, he served as Chief Business Officer at Igenica Biotherapeutics, Inc., an immunotherapy company. Prior to joining Igencia Biotherapeutics, Mr. Celebi served in various roles at ArQule, Inc., a biotechnology and pharmaceutical company from 2003 until 2011, including as Vice President of Business Development and New Product Planning and Alliance Management. Mr. Celebi received a B.S. in Biophysics from the University of California, San Diego and an M.B.A. from Carnegie Mellon University. We believe that Mr. Celebi's perspective and deep experience in the biotechnology industry, as well as his experience leading our company as the President and Chief Executive Officer, qualifies him to serve on our board of directors.

Anupama Hoey has served as our Chief Business Officer since October 2020. Prior to joining us, Ms. Hoey served as Chief Business Officer of Second Genome Inc., a biotechnology company, from July 2018 until June 2020. Prior to that, Ms. Hoey served as Chief Business Officer of Invenra Inc., a biotechnology company, from March 2017 until July 2018. Prior to Invenra, Ms. Hoey served as Vice President of Business Development of Arcus Biosciences, Inc. from November 2015 until December 2016. Ms. Hoey received a B.S. in Molecular Genetics from the Ohio State University, an M.S. from Case Western Reserve University and an M.B.A. from the University of San Francisco.

Marie-Louise Fjaellskog, M.D., Ph.D. has served as our Chief Medical Officer since June 2020. Prior to joining us, Dr. Fjaellskog served as Vice President, Clinical Development at Merus N.V., an immuno-oncology company from May 2019 until June 2020. Prior to joining Merus, Dr. Fjaellskog served as Vice President, Clinical Development at Infinity Pharmaceuticals, a biopharmaceutical company, from February 2018 until April 2019. From 2012 to February 2018, Dr. Fjaellskog held positions of increasing responsibility at Novartis, most recently as Global Clinical Program Leader. Dr. Fjaellskog has also served as an Associate Professor of Oncology at Uppsala University in Sweden since 2008, where she also received an M.D. and a Ph.D.

Robert Pierce, M.D. has served as our Chief Scientific Officer since March 2020. Prior to joining us, Dr. Pierce served as Scientific Director of the Immunopathology Lab in the Clinical Research Division of the Fred Hutchinson Cancer Research Center from November 2016 until March 2020. Prior to that, Dr. Pierce served as Chief Scientific Officer of OncoSec Medical Incorporated, a biotechnology company, from 2014 until June 2016. Dr. Pierce received a B.A. in Philosophy from Yale College and an M.D. from Brown University.

Erin Colgan has served as our Senior Vice President of Finance and Administration since January 2021 and previously served as our Vice President of Finance from July 2020 to January 2021. Prior to joining us, Ms. Colgan served as the Vice President of FP+A and Commercial Planning at Intarcia Therapeutics from August 2019 to June 2020. Prior to Intarcia, from August 2010 to August 2019, Ms. Colgan held various roles of increasing responsibility at Vertex Pharmaceuticals, most recently as Senior Director, FP+A and Global Revenue. Ms. Colgan began her career in public accounting at PricewaterhouseCoopers where she worked in both audit and business development. Ms. Colgan holds a B.A. in Accounting from the University of Massachusetts, Amherst.

Non-Employee Directors

Bob Holmen has served as a member of our board of directors since January 2017. Mr. Holmen provides legal services focused on venture capital and private equity markets to investors through his boutique law firm Investor Counsel, where he has served as a Principal since 2016. Mr. Holmen has also served as a Managing Director since 2001 and Chief Financial Officer since 2002 at Miramar Venture Partners, a venture capital firm, and as a Principal of Holmen Ventures, a strategic financial consulting firm, since 2013. Prior to Miramar, Mr. Holmen served as an Executive Officer for CoCensys, Inc., a biopharmaceutical company, and First Consulting Group, Inc., a healthcare consulting firm. Mr. Holmen received a B.S. in Electrical Engineering from Stanford University and a J.D. from University of California, Berkeley School of Law. We believe that Mr. Holmen's education and professional background in advising companies in the biotechnology industry qualifies him to serve on our board of directors.

James Peyer, Ph.D. has served as a member of our board of directors since January 2020. In September 2019, Dr. Peyer founded Cambrian Biopharma, where he serves as the Chief Executive Officer. In 2018, Dr. Peyer founded Cleara Biotech, a biopharmaceutical company, where he served as Executive Director from February 2018 to June 2019. Dr. Peyer also founded and served as Managing Partner at Apollo Health Ventures GmbH from June 2016 until March 2019. Prior to his service at Apollo Ventures, Dr. Peyer served as a consultant at McKinsey & Company from August 2015 until June 2016. Dr. Peyer received a B.A. in Biology from the University of Chicago and a Ph.D. in Stem Cell Biology at The University of Texas Southwestern Medical Center at Dallas. We believe that Dr. Peyer's experience in the biopharmaceutical industry, his years of business and leadership experience and expertise qualifies him to serve on our board of directors.

Samuel Broder, M.D. has served as a member of our board of directors since April 2019. Prior to his retirement, Dr. Broder was Senior Vice President from 2012 to June 2016 and Head of the Health Sector from 2015 to June 2016 for Intrexon Corporation, a synthetic biology company. Prior to Intrexon, he served as the Executive Vice President for Medical Affairs and Chief Medical Officer at Celera Corporation from 1998 to 2010. Prior to Celera, Dr. Broder served as Senior Vice President, Research and Development and Chief Scientific Officer at IVAX Corporation from 1995 to 1998. Dr. Broder served as the director of the National Cancer Institute from 1989 to 1995 appointed by President Ronald Reagan, where he oversaw the development of numerous anti-cancer therapeutic agents. Dr. Broder received a B.S. from University of Michigan and an M.D. from the University of Michigan Medical School, with post-graduate training at Stanford University in Palo Alto. We believe that Dr. Broder's significant scientific experience with therapeutic agents qualifies him to serve on our board of directors.

Thomas Ricks has served as a member of our board of directors since 2015. Mr. Ricks served as former Chief Investment Officer of H&S Ventures, LLC, a Forbes 150 family office, from 2001 until his retirement in 2018. Prior to his service, Mr. Ricks served as Chief Executive Officer of The University of Texas Investment Management Company from 1996 to 2001. Mr. Ricks has been a director of Ovintiv, Inc. since 2019 and currently serves as Chair of the Human Resources and Compensation Committee, and on the Corporate Responsibility and Governance Committee. He was a director of Newfield Exploration Company from 1992 to 2019 and most recently served as Chair of its Audit Committee. Mr. Ricks also served on the boards of several privately-held companies; BDM International (acquired by TRW), LifeCell Corporation, and Argus Pharmaceuticals. Mr. Ricks is a former director of the Ocean Institute, and a former member of the Investment Committees for St. David's Foundation and the University of California – Irvine Foundation. Mr. Ricks received a B.A. in Economics from Trinity College and an M.B.A. from the University of Chicago. We believe Mr. Ricks' extensive experience as a director of public company and private companies in the healthcare industry qualifies him to serve on our board of directors.

Deneen Vojta, M.D. has served as a member of our board of directors since January 2021. Dr. Vojta has served in various roles at UnitedHealth Group since 2006, including most recently as the Executive Vice President for Global Research & Development since 2016. Prior to UnitedHealth, she founded Mynetico, a company focused on the childhood obesity epidemic, and served as its Chief Executive Officer from 2003 to 2006. Prior to that, she served as the Chief Medical Officer of Health Partners from 1997 to 2000 and Frankford Health System from 2000 to 2003. Dr. Vojta received a B.S. from the University of Pittsburgh and an M.D. from Temple University School of Medicine. We believe that Dr. Vojta's significant scientific experience and experience as an executive of life sciences companies qualifies her to serve on our board of directors.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Composition of Our Board of Directors

Our business and affairs are managed under the direction of our board of directors. We have six directors serving as members of our board of directors. Our current directors will continue to serve as directors until their resignation, removal or successor is duly elected.

Our amended and restated certificate of incorporation and amended and restated bylaws permit our board of directors to establish the authorized number of directors from time to time by resolution. Each director serves until the expiration of the term for which such director was elected or appointed, or until such director's earlier death, resignation or removal. In accordance with our amended and restated certificate of incorporation, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be John Celebi and Samuel Broder, M.D., and their terms will expire at our first annual meeting of stockholders;
- the Class II directors will be Bob Holmen and Deneen Vojta, M.D., and their terms will expire at our second annual meeting of stockholders; and
- the Class III directors will be James Peyer, Ph.D. and Thomas Ricks, and their terms will expire at our third annual meeting of stockholders.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Our board of directors meets on a regular basis and additionally as required. The members of our current board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, our board of directors has determined that all of our directors except for Mr. Celebi do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of the Nasdaq Stock Market. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Party Transactions."

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our code of business conduct and ethics is available under the Corporate Governance section of our website at www.senseibio.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the Nasdaq Stock Market concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Form 10-K.

Audit Committee and Audit Committee Financial Expert

Our audit committee consists of Mr. Ricks, Mr. Holmen and Dr. Peyer. Our board of directors has determined that each of Mr. Ricks and Mr. Holmen satisfy the independence requirements under the listing standards of the Nasdaq Stock Market and Rule 10A-3(b)(1) of the Securities and Exchange Act of 1934, or the Exchange Act. Under Rule 10A-3 under the Exchange Act, we are permitted to phase in our compliance with the independent audit committee requirements set forth in Nasdaq Rule 5605(c) and Rule 10A-3 under the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Within one year of our listing on the Nasdaq Global Market, we expect that each director serving on the audit committee will satisfy the independence requirements under the applicable Nasdaq listing requirements and under Rule 10A-3 of the Exchange Act. The chair of our audit committee is Mr. Ricks, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each

member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Item 11. Executive Compensation.

Our named executive officers, consisting of our principal executive officer and the next two most highly compensated executive officers, as of December 31, 2020, were:

- John Celebi, our President and Chief Executive Officer;
- Robert Pierce, our Chief Scientific Officer; and
- Anupama Hoey, our Chief Business Officer.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers during the fiscal year ended December 31, 2020:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
John Celebi	2020	394,625	—	1,775,500	118,965	19,040 (5)	2,308,130
President and Chief Executive Officer							
Robert Pierce(2)	2020	266,806	—	670,000	102,000	32,780 (6)	1,071,586
Chief Scientific Officer							
Anupama Hoey(3)	2020	74,529	25,000 (4)	1,250,000	22,118	—	1,371,647
Chief Business Officer							

(1) The amounts disclosed represent the aggregate grant date fair value of the awards granted to our named executive officers during 2020 under our 2018 Plan, computed in accordance with ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards are set forth in Note 10 to our audited consolidated financial statements included elsewhere in this Form 10-K. This amount does not reflect the actual economic value that may be realized by the named executive officer.
(2) Dr. Pierce joined as our Chief Scientific Officer in March 2020.
(3) Ms. Hoey joined as our Chief Business Officer in October 2020.
(4) Pursuant to her employment agreement, Ms. Hoey received a $25,000 signing and retention bonus upon joining our company, as further described below in "—Employment Agreements with our Named Executive Officers."
(5) Includes 401(k) plan matching contributions, a housing allowance and a vehicle allowance.
(6) Includes 401(k) plan matching contributions, a housing allowance, and a payment in connection with our acquisition of Alvaxa as further described in "Certain Relationships and Related Party Transactions—Business Combination."

Narrative to the Summary Compensation Table

Annual Base Salary

Our named executive officers receive a base salary to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Mr. Celebi's annual base salary was $385,000 from January 1, 2020 to March 31, 2020 and was $396,550 from April 1, 2020 to December 31, 2020. The base salaries for Dr. Pierce and Ms. Hoey during 2020 were $340,000 and $345,000, respectively.

Bonus

Our named executive officers are eligible to receive annual bonuses of up to a percentage of the applicable executive's gross base salary based on performance metrics, as determined by our board of directors. For 2020, the target bonus for each of Mr. Celebi, Dr. Pierce and Ms. Hoey was 30% of their respective base salaries. For 2020, our board of directors determined that the corporate performance goals had been achieved at a 100% level in the aggregate.

Employment Agreements with our Named Executive Officers

Below are descriptions of our employment agreements with our named executive officers. The agreements generally provide for at-will employment and set forth the named executive officer's initial base salary, eligibility for employee benefits and severance benefits upon a qualifying termination of employment. Furthermore, each of our named executive officers has executed a form of our standard proprietary information and inventions assignment agreement. The key terms of the employment agreements with our named executive officers, including potential payments upon termination or change of control, are described below. We have also entered into new employment agreements with our named executive officers, which were effective upon the closing of our initial public offering, as described further below under "—Post IPO Employment Agreements."

John Celebi

On January 1, 2021, we entered into an amended and restated executive employment agreement with John Celebi, or the Celebi Employment Agreement, which provides for his continued at will employment as our President and Chief Executive Officer, with no specific term. The Celebi Employment Agreement provides for an annual base salary of $395,000, which amount is subject to review and adjustment from time to time, an annual discretionary bonus of up to 30% of this base salary, the amount of which will be decided in the sole discretion of our board of directors based upon our and Mr. Celebi's achievement of objectives and milestones determined on an annual basis by our board of directors, and reimbursement for reasonable travel expenses for so long as Mr. Celebi's primary residence is in Connecticut, not to exceed $4,000 per month.

In the event of his termination without cause (as such term is defined in the Celebi Employment Agreement) or resignation for good reason (as such term is defined in the Celebi Employment Agreement), Mr. Celebi shall be entitled to (i) salary continuation for the nine month period following such termination, or the Severance Period, provided that such salary continuation will be reduced by 50% of any amounts Mr. Celebi receives as salary from any other entity within the life sciences industry during the Severance Period, (ii) any annual bonus declared but not yet paid, (iii) accelerated vesting of the portion of her time-based equity awards that would have otherwise vested during the nine-month period following the termination and (iv) continuation of medical insurance through the Severance Period at no cost to Mr. Celebi, unless he begins subsequent employment prior to the end of such nine-month period. The foregoing severance benefits are conditioned upon Mr. Celebi's execution of a separation agreement, including a release of claims and compliance with certain restrictive covenants.

Robert Pierce

On February 9, 2020, we entered into an executive employment agreement with Robert Pierce, or the Pierce Employment Agreement, which provides for his at will employment as our Chief Scientific Officer, with no specific term. The Pierce Employment Agreement provides for an annual base salary of $340,000, which amount is subject to review and adjustment from time to time, an annual discretionary bonus of up to 30% of this base salary, the amount of which will be decided in the sole discretion of our board of directors based upon our and Dr. Pierce's achievement of objectives and milestones determined on an annual basis by our board of directors, and a one-time bonus in the event that Dr. Pierce is required to repay to Fred Hutchinson Cancer Research Center, or FHCRC, a portion of the home loan forgiveness provided by FHCRC. The Pierce Employment Agreement also provides for relocation expense reimbursement of up to $25,000, a housing stipend and repayment of certain other business-related expenses.

In the event of his termination without cause (as such term is defined in the Pierce Employment Agreement), Dr. Pierce shall be entitled to (i) salary continuation for the Severance Period, (ii) any annual bonus declared but not yet paid, (iii) accelerated vesting of the portion of his time-based equity awards that would have otherwise vested during the six-month period following the termination, (iv) any accrued but unpaid expenses and (v) continuation of medical insurance through the Severance Period at no cost to Dr. Pierce, unless he begins subsequent employment prior to the end of the Severance Period. The foregoing severance benefits are conditioned upon Dr. Pierce's execution of a separation agreement, including a release of claims and compliance with certain restrictive covenants.

Anupama Hoey

On October 13, 2020, we entered into an employment agreement with Anupama Hoey, or the Hoey Employment Agreement, which provides for her at-will employment as our Chief Business Officer, with no specific term. The Hoey Employment Agreement provides for an annual base salary of $345,000, which amount is subject to review and adjustment from time to time, and an annual

discretionary bonus of up to 30% of this base salary, the amount of which will be decided in the sole discretion of our board of directors based upon our and Ms. Hoey's achievement of objectives and milestones determined on an annual basis by our board of directors. The Hoey Employment Agreement also provides for a signing and retention payment of $25,000, which we paid to Ms. Hoey in October 2020, and which is subject to repayment if Ms. Hoey's employment terminates prior to October 14, 2021 other than in the event of her termination without cause or if Ms. Hoey terminates her employment for good reason (as such terms are defined in the Hoey Employment Agreement).

In the event of her termination without cause or if Ms. Hoey terminates her employment for good reason, Ms. Hoey shall be entitled to (i) an amount equal to Ms. Hoey's then current salary for six months, (ii) accelerated vesting of the portion of her time-based equity awards that would have otherwise vested during the six-month period following the termination, (iii) any accrued and unpaid business expenses, and (iv) continuation of medical insurance for six months at no cost to Ms. Hoey, unless she begins subsequent employment prior to the end of such Severance Period. The foregoing severance benefits are conditioned upon Ms. Hoey's execution of a separation agreement, including a release of claims and compliance with certain restrictive covenants.

Post-IPO Employment Agreements

In January 2021, we entered into new employment agreements with our named executive officers, which became effective upon the closing of our initial public offering. The agreements generally provide for at-will employment and set forth the named executive officer's base salary, target bonus and eligibility for employee benefits and severance benefits upon a qualifying termination of employment. Under the new agreements, Mr. Celebi's, Dr. Pierce's and Ms. Hoey's annual base salaries are $500,000, $420,000 and $365,000, respectively, subject to review and revision by our board of directors. In addition, the target bonus for each of Mr. Celebi, Dr. Pierce and Ms. Hoey will be up to 55%, 40% and 40%, respectively, of their respective base salaries, subject to review and revision by our board of directors.

The new employment agreements provide that, subject to certain conditions and limitations, upon the termination of the employment of an eligible executive officer without Cause or resignation for Good Reason (each, as defined in the employment agreements) not in connection with a Change in Control (as defined in the 2018 Plan):

- Dr. Pierce and Ms. Hoey will be eligible to receive a cash severance benefit equal to nine months' base salary; Mr. Celebi will be eligible to receive a cash severance benefit equal to 12 months' base salary; and
- such executive officer shall be eligible to receive COBRA premiums for the applicable length of the severance period as described above.

In addition, the new employment agreements provide that, subject to certain conditions and limitations, upon the termination of the employment of an eligible executive officers without Cause or resignation for Good Reason (each, as defined in the employment agreements) within 12 months following a Change in Control:

- Dr. Pierce and Ms. Hoey will be eligible to receive a cash severance benefit equal to 12 months' base salary and 100% of the officer's target bonus; Mr. Celebi will be eligible to receive a cash severance benefit equal to 18 months' base salary and 150% of his target bonus;
- all unvested equity awards held by such executive officer will become immediately vested and fully exercisable; and
- such executive officer shall be eligible to receive COBRA premiums for the applicable length of the severance period as described above.

The severance benefits described above are conditioned upon the executive officer's execution and non-revocation of a separation agreement, including a release of claims, and compliance with certain restrictive other obligations.

Equity-Based Incentive Awards

We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have only used stock option grants for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. The use of stock options also can provide tax and other advantages to our executive officers relative to other forms of equity compensation. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees.

We award stock options broadly to our employees, including to our non-executive employees. Grants to our executives and other employees are made at the discretion of our board of directors and are not made at any specific time period during a year.

Prior to our initial public offering, all of the stock options we have granted were made pursuant to our 2018 Plan. In the future we will grant equity incentive awards under the terms of our 2021 Equity Incentive Plan, or 2021 Plan. The terms of our equity plans are described under the section titled "—Equity Incentive Plans" below.

Outstanding Equity Awards as of December 31, 2020

The following table presents estimated information regarding outstanding equity awards held by our named executive officers as of December 31, 2020. All awards were granted pursuant to the 2018 Plan. See the section titled "—Equity Incentive Plans—2018 Stock Incentive Plan" below for additional information.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
John Celebi	—	559,375 (1)	$ 3.22	08/04/2030
President and Chief Executive Officer	18,333	8,333 (2)	$ 122.88	04/01/2028
Robert Pierce	—	208,333 (3)	$ 3.22	08/04/2030
Chief Scientific Officer	499	21 (4)	$ 122.88	01/21/2029
Anupama Hoey	—	208,333 (5)	$ 6.00	12/28/2030
Chief Business Officer				

(1) The unvested shares underlying this option vest as to 25% of the shares on February 15, 2021, with the remainder vesting in 36 equal monthly installments thereafter, subject to the officer's continued service through each applicable vesting date.
(2) The unvested shares underlying this option vest in 15 equal monthly installments until March 1, 2022, subject to the officer's continued service through each applicable vesting date.
(3) The unvested shares underlying this option vest as to 25% of the shares on March 18, 2021, with the remainder vesting in 36 equal monthly installments thereafter, subject to the officer's continued service through each applicable vesting date.
(4) The unvested shares underlying this option vest on January 22, 2021, subject to the officer's continued service through each applicable vesting date.
(5) The unvested shares underlying this option vest as to 25% of the shares on October 14, 2021, with the remainder vesting in 36 equal monthly installments thereafter, subject to the officer's continued service through each applicable vesting date.

Employee Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans and our 401(k) plan are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which, other than the 401(k) plan, are filed as exhibits to the registration statement of which this Form 10-K is a part.

2021 Equity Incentive Plan

Our board of directors adopted our 2021 Plan on January 27, 2021 and our stockholders approved our 2021 Plan on January 28, 2021. Our 2021 Plan provides for the grant of incentive stock options, or ISOs, to employees, including employees of any of our parent or subsidiary corporations, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of our affiliates. Our 2021 Plan is a successor to the 2018 Plan, and became effective on the execution of the underwriting agreement related to our initial public offering.

Authorized Shares. Initially the maximum number of shares of our common stock that may be issued under our 2021 Plan was the sum of (i) 2,469,935 new shares; plus (ii) the number of shares that remain available for issuance under our 2018 Plan at the time our 2021 Plan becomes effective; and (iii) any shares subject to outstanding stock options or other stock awards that were granted under our 2018 Plan that are forfeited, terminate, expire or are otherwise not issued. In addition, the number of shares of our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, in an amount equal to 4.0% of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of

directors. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan is 10,000,000 shares.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2021 Plan. Additionally, shares become available for future grant under our 2021 Plan if they were issued pursuant to stock awards granted under our 2021 Plan and we repurchase such shares or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, administers our 2021 Plan. The plan administrator may also delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, the plan administrator has the authority to determine and amend the terms of awards and underlying agreements, including:

- the recipients;
- the exercise, purchase or strike price of stock awards, if any;
- the number of shares subject to stock awards;
- the vesting schedule applicable to stock awards, together with any vesting acceleration; and
- the form of consideration, if any, payable on exercise or settlement of stock awards.

Under the 2021 Plan, the plan administrator also generally has the authority to effect, with the consent of any adversely affected participant:

- the reduction of the exercise, purchase, or strike price of any outstanding stock award;
- the cancellation of any outstanding stock award and the grant in substitution therefore of other stock awards, cash, or other consideration; or
- any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2021 Plan; provided, that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our equity incentive plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the option is not exercisable after the expiration of five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock units are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock units may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally

cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2021 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

Performance Awards. The 2021 Plan permits the grant of performance-based stock and cash awards. The plan administrator may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. The performance criteria that will be used to establish such performance goals may be based on any measure of performance selected by the plan administrator. The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including stock awards granted and cash fees paid by us to such non-employee director, will not exceed $750,000 in total value, or in the event such non-employee director is first appointed or elected to the board during such annual period, $1,000,000 in total value (in each case, calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes); provided, that the foregoing limitations will not apply during the year in which the 2021 Plan is first adopted.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2021 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of incentive stock options, and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2021 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant. In the event of a corporate transaction, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the transaction (contingent upon the effectiveness of the transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the transaction). With respect to performance awards with multiple vesting levels depending on performance level, unless otherwise provided by an award agreement or by the administrator, the award will accelerate at 100% of target. If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by persons other than current participants, such awards will terminate if not exercised (if applicable) prior to the effective time of the transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the transaction. The plan administrator is not obligated to treat all

stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants. In the event a stock award will terminate if not exercised prior to the effective time of a transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award over (ii) any exercise price payable by such holder in connection with such exercise.

Under our 2021 Plan, a corporate transaction is defined to include: (i) a sale of all or substantially all of our assets, (ii) the sale or disposition of more than 50% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding before such transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder.

Change in Control. In the event of a change in control, as defined under our 2021 Plan, awards granted under our 2021 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Under the 2021 Plan, a change in control is defined to include (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity); (iii) the approval by our stockholders or our board of directors of a plan of complete dissolution or liquidation of the company, or the occurrence of a complete dissolution or liquidation of the company, except for a liquidation into a parent corporation; (iv) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders; and (v) an unapproved change in the majority of our board of directors.

Transferability. A participant may not transfer stock awards under our 2021 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2021 Plan.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan; provided, that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

2021 Employee Stock Purchase Plan

Our board of directors adopted, and our stockholders approved, our 2021 Employee Stock Purchase Plan, or the ESPP, in January 2021. The ESPP became effective on the execution of the underwriting agreement related to our initial public offering. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code for U.S. employees.

Share Reserve. Following our initial public offering, the ESPP authorizes the issuance of 333,333 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 through January 1, 2031, by 1.0% of the total shares of our common stock outstanding on December 31st of the preceding calendar year, or the Evergreen Measurement Date; provided, that (i) the number of shares added to the share reserve will be reduced automatically to the extent necessary to avoid causing the share reserve to exceed a number of shares equal to 1.0% of the shares of our common stock outstanding on the applicable Evergreen Measurement Date and (ii) our board of directors may act prior to the first day of any calendar year to provide that there will be no January 1st increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of our common stock than would otherwise occur.

Administration. Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first date of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase. For the initial public offering, which we expect will commence on the execution and delivery of the underwriting agreement relating to our initial public offering, the fair market value on the first day of the offering period will be the price at which shares of common stock are first sold to the public.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (i) the number of shares reserved under the ESPP; (ii) the maximum number of shares by which the share reserve may increase automatically each year; (iii) the number of shares and purchase price of all outstanding purchase rights; and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of 90% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately.

Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

2018 Stock Incentive Plan

Our board of directors and our stockholders approved the 2018 Plan, which became effective in March 26, 2018. The 2018 Plan provides for the grant of ISOs to our employees and our parent and subsidiary corporations' employees, and for the grant of NSOs, restricted stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Following the effectiveness of the 2021 Plan, no additional awards will be granted under the 2018 Plan. Any outstanding awards granted under our 2018 Plan will remain subject to the terms of our 2018 Plan and applicable award agreements.

Authorized Shares. As of December 31, 2020, a total of 2,552,083 shares of our common stock were reserved for issuance under the 2018 Plan. As of December 31, 2020, 1,947,123 shares of our common stock were subject to outstanding option awards.

Administration. Our board of directors or a duly authorized committee of our board of directors administers the 2018 Plan and the stock awards granted under it. Under the 2018 Plan, the administrator has the authority to: (i) construe and interpret the 2018 Plan and any agreement thereunder; (ii) to determine the fair market value of our common stock; (iii) to select award recipients; (iv) to determine whether an option will be an ISO or an NSO; (v) to determine the number of shares subject to awards; (vi) to establish the terms and conditions of the awards; (vii) to amend, cancel, accept the surrender of, or modify any award; (viii) to accelerate the vesting of or terminate the restrictions of an award; (ix) to amend the terms of an award agreement, as required by the Internal Revenue Code of 1986, as amended, or the Code, or with the consent as the participant, as applicable; and (x) to establish policies and procedures for the exercise of awards.

Stock Options. ISOs and NSOs were granted pursuant to award agreements adopted by the plan administrator. The plan administrator determined the exercise price for a stock option, within the terms and conditions of the 2018 Plan; provided, that the exercise price of an ISO generally cannot be less than 100% (or 110% in the case of ISOs granted to certain stockholders) of the fair market value of our common stock on the date of grant. Options granted under the 2018 Plan vest at the rate specified by the plan administrator. Payment for the purchase of common stock issued upon the exercise of an option may be made (i) in cash; (ii) by good check payable to the Company or electronic funds transfer of immediately available funds to the Company; or (iii) in accordance with the terms of the applicable award agreement. The plan administrator determines the term of stock options granted under the 2018 Plan, up to a maximum of 10 years in the case of ISOs (or five years in the case of ISOs granted to certain stockholders).

Changes in Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock dividend, division, combination, reclassification or similar change in the capital structure of the Company, appropriate adjustments will be made to (i) the number of shares authorized or reserved for issuance under the 2018 Plan; and (ii) the exercise prices of and number of shares subject to outstanding awards under the 2018 Plan.

Transferability. A participant may not transfer stock awards under our 2018 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2018 Plan or an award granted thereunder.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a nonqualified deferred compensation plan sponsored by us during fiscal 2020.

Termination or Change in Control Benefits

Our named executive officers may become entitled to certain benefits in connection with a qualifying termination. Each of our named executive officers' employment agreements entitles them to certain benefits, upon a qualifying termination. For additional discussion, please see "Employment Agreements with our Named Executive Officers."

Health and Welfare; Perquisites

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, disability and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances (including Mr. Celebi's housing and vehicle allowances and Dr. Pierce's housing allowance).

401(k) Plan

We maintain a safe harbor 401(k) plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain limits of the Code, which are updated annually. We have the ability to make matching and discretionary contributions to the 401(k) plan. Currently, make matching contributions or discretionary contributions to the 401(k) plan up to a maximum of 4% of such employee's annual compensation. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not generally taxable to the employees until withdrawn or distributed from the 401(k) plan.

Non-Employee Director Compensation

With the exception of the payments provided pursuant to the consulting arrangement described below, prior to our initial public offering, we had not historically paid cash retainers or other cash compensation with respect to service on our board of directors, except for reimbursement of direct expenses incurred in connection with attending meetings of the board or committees.

The following table sets forth information regarding the compensation earned or paid to our non-employee directors during the year ended December 31, 2020. John Celebi, our President and Chief Executive Officer, is also a member of our board of directors,

but did not receive any additional compensation for service as a director. The compensation of Mr. Celebi as a named executive officer is set forth below under "Executive Compensation—Summary Compensation Table."

Name	Option Awards ($)(1)(2)	All Other Compensation ($)	Total ($)
Bob Holmen	188,337	—	188,337
James Peyer, Ph.D.	62,779	—	62,779
Samuel Broder, M.D.	62,779	84,000 (3)	146,779
Thomas Ricks	62,779	—	62,779

(1) Amounts reported represent the aggregate grant date fair value of option awards granted to our directors during 2020 under our 2018 Stock Incentive Plan, as amended, or 2018 Plan, computed in accordance with Financial Accounting Standard Board Accounting Standards Codification, Topic 718, or ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our audited consolidated financial statements included elsewhere in this Form 10-K. This amount does not reflect the actual economic value that may be realized by the non-employee director.

(2) As of December 31, 2020, Mr. Holmen, Dr. Peyer, Dr. Broder and Mr. Ricks held options to purchase 43,145, 19,520, 20,145 and 20,770 shares of our common stock, respectively.

(3) Consists of payments pursuant to the consulting arrangement described below.

Non-Employee Director Compensation Policy

Our board of directors adopted a non-employee director compensation policy in January 2021 that is applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director will receive the compensation described below for service on our board of directors:

Cash compensation. Under this policy, we will pay each of our non-employee directors cash retainers for service on our board of directors and committees of our board of directors as follows:

	Annual Cash Retainer ($)
Annual retainer	35,000
Additional retainer for independent chair	30,000
Additional retainer for audit committee chair	15,000
Additional retainer for audit committee non-chair member	7,500
Additional retainer for compensation committee chair	10,000
Additional retainer for compensation committee non-chair member	5,000
Additional retainer for nominating and corporate governance committee chair	8,000
Additional retainer for nominating and corporate governance committee non-chair member	4,000

Equity compensation. In addition to cash compensation, each non-employee director will be eligible to receive options under our 2021 Plan. Any options granted under this policy will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of service. Vesting schedules for equity awards will be subject to the non-employee director's continuous service on each applicable vesting date, provided that each option will vest in full upon a change in control of the company, as defined in the 2021 Plan.

Initial award. Each new non-employee director elected or appointed to our board of directors after the effective date of the policy will be granted an initial, one-time option to purchase 16,666 shares of our common stock, which will vest in equal monthly installments such that the option is fully vested on the third anniversary of the grant date. On the date of the pricing of our initial public offering, each non-employee director received an option to purchase 16,666 shares of our common stock with an exercise price of $19.00 per share, which will vest in equal monthly installments such that the option is fully vested on the third anniversary of the grant date.

Annual awards. On the date of each annual meeting of stockholders of our company after the effective date of the policy, each non-employee director that continues to serve on our board of directors will be granted an option to purchase 8,333 shares of our common stock, which will vest in equal monthly installments such that the option is fully vested on the first anniversary of the grant date, provided that such option will in any case become fully vested on the date of our next annual stockholder meeting.

Consulting Arrangements

In May 2018, we entered into an Independent Contractor and Strategic Advisory Services Agreement with Samuel Broder, M.D., pursuant to which Mr. Broder received $7,000 per month. We entered into an amended agreement as of April 5, 2020, pursuant to which Mr. Broder receives $7,000 per month.

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

The following table sets forth certain information regarding the ownership of our common stock as of March 1, 2021 by: (i) each director; (ii) each of the executive officers listed in the Summary Compensation Table; (iii) all currently serving executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock. Except as otherwise noted below, the address for persons listed in the table is c/o Sensei Biotherapeutics, Inc., 1405 Research Blvd, Suite 125, Rockville, Maryland 20850.

Beneficial Owner (1)	Number of Shares Beneficially Owned	Percent of Shares Beneficially Owned
Greater than 5% Stockholders:		
Cambrian BioPharma Inc. (2)	4,780,292	15.6 %
Future Ventures, L.P. (3)	1,601,247	5.2
H&S Investments I, L.P. (4)	4,441,622	14.5
Named Executive Officers and Directors:		
John Celebi (5)	183,706	*
Robert Pierce, M.D. (6)	130,406	*
Anupama Hoey	—	—
Bob Holmen (7)	33,895	*
James Peyer, Ph.D. (2)	4,780,292	15.6
Samuel Broder, M.D. (5)	12,123	*
Thomas Ricks (8)	315,974	1.0
Deneen Vojta, M.D. (5)	925	*
All current directors and executive officers as a group (10 persons)	5,457,321	17.7

*Less than one percent.

(1) This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D and 13G if any filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 30,588,495 shares outstanding on March 1, 2021, adjusted as required by rules promulgated by the SEC.

(2) Consists of 4,768,794 shares of common stock and 11,498 shares issuable pursuant to stock options exercisable within 60 days following March 1, 2021 held by Cambrian Biopharma Inc, or Cambrian. Cambrian is a Delaware corporation and Mr. Peyer serves as Cambrian's Chief Executive Officer. In such capacity Mr. Peyer may direct the voting and disposition of the shares held by Cambrian, subject in certain instances to the approval of Cambrian's Board of Directors. Cambrian's business address is 19 Morris Avenue, Brooklyn Navy Yard, Building 128, Brooklyn, New York 11025.

(3) Consists of 1,505,746 shares of common stock held by Future Ventures, L.P. and 95,501 shares of common stock held by Future Ventures Side Fund, L.P. The shares directly held by Future Ventures L.P. and Future Ventures Side Fund, L.P. are indirectly held by Future Ventures GP, LLC, the general partner of Future Ventures, L.P. and Future Ventures Side Fund, L.P. The managing members of Future Ventures GP, LLC are Maryanna Saenko and Steve Jurvetson. Future Ventures GP, LLC, Maryanna Saenko and Steve Jurvetson may be deemed to have voting and dispositive power with respect to the shares held by Future Ventures, L.P. and Future Ventures Side Fund, L.P. The principal business address of Future Ventures, L.P. and Future Ventures Side Fund, L.P. is 465 1st Street, Los Altos, California 94022.

(4) Consists of 4,425,998 shares of common stock and warrants exercisable for 15,624 shares of common stock held by H&S Investments I, L.P. H&S Ventures, LLC, its general partner, and Michael Schulman, manager of H&S Ventures, may be deemed to have voting and dispositive power with respect to the shares held. The principal business address of H&S Investments I, L.P. is 2101 E Coast Highway 3rd Floor Corona Del Mar, CA 92625.

(5) Consists of shares issuable pursuant to stock options exercisable within 60 days following March 1, 2021.

(6) Consists of 73,463 shares of common stock and 56,943 shares issuable pursuant to stock options exercisable within 60 days following March 1, 2021.
(7) Consists of 16,666 shares of common stock and 17,229 shares issuable pursuant to stock options exercisable within 60 days following March 1, 2021.
(8) Consists of 301,769 shares of our common stock and a warrant to purchase 1,457 shares of our common stock held by Ricks Family Trust, and 12,748 shares issuable pursuant to stock options exercisable within 60 days following March 1, 2021 held by Thomas Ricks. Thomas Ricks is a trustee of the Ricks Family Trust and accordingly may be deemed to have voting and dispositive power with respect to the shares held by Ricks Family Trust.

Equity Compensation Plan Information

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2020:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (1))
Equity compensation plans approved by security holders:			
2018 Plan	1,951,525	$ 5.70	600,558
Equity compensation plans not approved by security holders	465,072	$ 9.58	—
Total	2,416,597		600,558

(1) Effective upon our initial public offering, no additional further options or awards may be granted under the 2018 Plan; all outstanding stock awards will continue to be governed by their existing terms. For a description of the terms of our 2018 Plan, see the section above titled "Executive Compensation–Equity Incentive Plans—2018 Stock Incentive Plan."

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

Other than compensation arrangements for our directors and executive officers, which are described elsewhere in this Form 10-K, below we describe transactions since January 1, 2019 to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our voting securities, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Series BB Convertible Preferred Stock Financing

From December 2020 through January 2021, we issued an aggregate of 165,956,208 shares of our Series BB convertible preferred stock at a purchase price of $0.207383 per share for an aggregate gross proceeds of $34.4 million in cash. The following table summarizes purchases of convertible preferred stock by holders of more than five percent of our voting securities and their affiliated entities, our directors and our executive officers.

Name	Series BB Preferred Stock(1)
Cambrian BioPharma, Inc.	4,821,996
Entities affiliated with Future Ventures	8,679,592
Entities affiliated with Presight Capital	28,931,976
Ricks Family Trust	3,037,849

(1) Upon the closing of our initial public offering, each share of our Series BB preferred stock converted into one share of common stock.

Series AA Convertible Preferred Stock and Warrant Financing

From January 2020 through the date of this Form 10-K, we issued an aggregate of 747,683,172 shares of our Series AA convertible preferred stock to a total of 128 accredited investors at a price per share of $0.082135 per share. We received aggregate gross proceeds of $26.1 million for the sale of 317,608,273 shares of Series AA convertible preferred stock. The redemption of convertible notes resulted in the issuance of 219,764,874 shares of Series AA convertible preferred stock. In exchange for our convertible preferred stock series A through F, including cumulative and unpaid dividends, we issued 210,310,025 shares of Series AA convertible preferred stock as part of the Recapitalization. In connection with the issuance or our Series AA convertible preferred stock, (1) the principal and accrued interest under the Secured Note, the Existing Stockholder Notes and the Existing Bridge Note described below under the heading "—Convertible Note and Warrant Financings" converted into an aggregate of 219,764,874 shares of our Series AA convertible preferred stock, (2) we issued warrants to purchase an aggregate of 1,530,737 shares of our common stock, (3) accrued and unpaid dividends payable to holders of our convertible preferred stock, and (4) immediately prior to the issuance of our Series AA convertible preferred stock, all shares of convertible preferred stock then outstanding were converted into 210,310,025 shares of our common stock. In connection with the issuance of our Series AA convertible preferred stock, certain purchasers of Series AA convertible preferred stock were entitled to convert certain shares of common stock held by such purchaser into shares of Series AA convertible preferred stock. The following table summarizes purchases of convertible preferred stock by holders of more than five percent of our voting securities and their affiliated entities, our directors and our executive officers, as well as the number of shares of common stock such persons received upon conversion of shares of our then-outstanding convertible preferred stock.

Name	Series AA Convertible Preferred Stock(1)	Shares of Common Stock
Cambrian BioPharma, Inc.	110,729,827 (2)	—
Entities affiliated with Future Ventures	66,962,926	—
H&S Investments I, L.P.	209,368,245	34,998
Entities affiliated with Presight Capital	48,974,005	—

(1) Immediately prior to the closing of our initial public offering, each share of our Series AA convertible preferred stock converted into one share of common stock. For a description of the material rights and privileges of the convertible preferred stock, see Note 8 to our audited consolidated financial statements included elsewhere in this Form 10-K.

(2) Includes shares acquired upon exercise of warrants in January 2021 issued in connection with the financing.

Convertible Note and Warrant Financings

Transferred Note

In March 2020, Cambrian BioPharma, Inc., or Cambrian, purchased an outstanding convertible promissory note issued by us to a prior investor and, as a result, we issued a replacement convertible promissory note, or the Transferred Note, to Cambrian in the principal amount of $1.0 million.

In November 2020, Cambrian converted the Transferred Note into 31,591,824 shares of our Series AA convertible preferred stock.

Existing Bridge Note

In November 2019, we issued an unsecured convertible promissory note, or the Existing Bridge Note, to Cambrian, in a principal amount of $1.0 million. The Existing Bridge Note converted into shares of our Series AA convertible preferred stock in the Series AA convertible preferred stock and warrant financing described above.

Secured Note

In September 2019, we issued a secured convertible promissory note, or the Secured Note, to H&S Investments I, L.P., or H&S, in a principal amount of up to a maximum of $3.0 million to be paid in installments. Pursuant to the terms of the Secured Note, H&S paid two installments, equal to an aggregate principal amount of $1.5 million. Prior to the payment of all required installments, the Secured Note converted into shares of our Series AA convertible preferred stock in the Series AA convertible preferred stock and warrant financing described above.

In connection with the issuance of the Secured Note, we entered into a Security Agreement with H&S, providing for a security interest in all of our (1) goods and equipment, (2) inventory, (3) contract rights and general intangibles, (4) accounts, accounts

receivable, royalties, license rights and all other forms of obligation arising out of the sale or leads or good, the licensing of technology or the rendering of services, (4) commercial tort claims, (5) documents, cash, deposit accounts, securities, investment property, letters of credit, certificates of deposit, instruments, chattel paper and supporting obligation, (6) all patents and patent application, and (7) any claims, rights and interests in any of the aforementioned property.

Existing Stockholder Notes and Warrants

From December 2018 to November 2019, we issued unsecured convertible promissory notes, or collectively, the Existing Stockholder Notes, to certain of our existing stockholders in an aggregate principal amount of $11.4 million. In connection with the issuance of the Existing Stockholder Notes, we issued warrants to purchase an aggregate of 26,823 shares of our common stock to the holders of the Existing Stockholder Notes. The following table summarizes purchases of our Existing Stockholder Notes and the issuance of the related warrants to purchase common stock by our directors, executive officers and holders of more than 5% of any class of our capital stock:

Name	Principal Amount of Existing Stockholder Notes	Warrants to Purchase Common Stock
H&S Investments I, L.P.	$ 3,000,000	15,624
Ricks Family Trust	$ 375,000	1,457

The Existing Stockholder Notes converted into shares of our Series AA convertible preferred stock in the Series AA convertible preferred stock and warrant financing described above.

Investors' Rights Agreement

We are party to an investors' rights agreement, or IRA with certain holders of our convertible preferred stock, including our 5% stockholders and their affiliates. The IRA provides these stockholders with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing, and also the right to obligate us to an agreement to provide for additional rights to demand that we file a registration statement or request that their shares be covered by a registration statement that we have filed and maintain as effective. The IRA provided these stockholders with information rights, which terminated immediately before consummation of our initial public offering.

Consulting Agreement

In December 2020, we entered into a consulting agreement with Apeiron Advisory Ltd., or Apeiron Advisory, an affiliate of Presight Sensei Co-Invest Fund, L.P., one of the holders of more than 5% of our voting securities. Pursuant to the consulting agreement, Apeiron Advisory provided us with strategic and development-related advice in exchange for a one-time retaining fee of $1.5 million, which we paid to Apeiron Advisory in January 2021.

Business Combination

In May 2020, we entered into a Stock Purchase Agreement to purchase 100% of the shares of Alvaxa. Dr. Pierce, the Company's Chief Scientific Officer, and his spouse together held a majority of the shares of Alvaxa. Under the Stock Purchase Agreement, we paid an aggregate of $0.2 million and issued 304,376 shares of our common stock to the shareholders of Alvaxa. Dr. Pierce and his spouse collectively received $70,336 and 169,286 shares of our common stock in connection with the acquisition.

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see the section titled "Executive Compensation—Limitations of Liability and Indemnification Matters."

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Director Independence

As required under the Nasdaq listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the Board. The Board consults with our counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and our company, senior management and independent auditors, the Board has affirmatively determined that all of our directors are independent directors within the meaning of the applicable Nasdaq listing standards with the exception of Mr. Celebi. In making these determinations, the Board found that none of these directors or nominees for director had a material or other disqualifying relationship with our company.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2020 and 2019 by our principal accountants. All such fees described below were approved by the audit committee.

(in thousands)

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2019
Audit fees(1)	$ 412	$ 230
Audit-related fees(2)	1,304	—
Tax fees(3)	30	26
Total	$ 1,746	$ 256

(1) Audit fees consists of fees billed or incurred for professional services rendered in connection with the audit of our consolidated financial statements and review of the interim condensed consolidated financial statements included in our quarterly reports.
(2) Audit-related fees includes fees billed or incurred for professional services rendered in connection with our initial public offering.
(3) Tax fees includes services related to the preparation or review of the U.S. federal, state and local tax returns, and other advisory and professional services.

All fees described above were pre-approved by our audit committee following our initial public offering or by our Board of Directors.

Our audit committee has adopted a policy and procedures for the pre-approval of audit and, if applicable, non-audit services rendered by our independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services, and tax services up to specified amounts. Pre-approval may also be given as part of the audit committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual explicit case-by-case basis before the independent registered public accounting firm is engaged to provide each service. On a periodic basis, the independent registered public accounting firm reports to the audit committee on the status of actual costs for approved services against the approved amounts.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(3) Exhibits

Exhibit Number	Description
2.1+^	Stock Purchase Agreement, by and among Sensei Biotherapeutics, Inc. and the stockholders of Alvaxa Biosciences, Inc., dated as of May 18, 2020 (incorporated by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
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 (File No. 001-39980), filed with the SEC on February 11, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39980), filed with the SEC on February 11, 2021).
4.1	Investors' Rights Agreement, dated as of December 29, 2020, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
4.2	Forms of Warrant to Purchase Common Stock (incorporated by reference to Exhibits 4.2, 4.3 and 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
4.3*	Description of Securities.
10.1#	Sensei Biotherapeutics, Inc. 2018 Equity Incentive Plan, as amended, and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.2#	Sensei Biotherapeutics, Inc. 2021 Equity Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.3+	Non-exclusive License Agreement, by and between Alvaxa Biosciences, Incorporated and Fred Hutch Cancer Research Center, dated as of January 3, 2020 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.4#	Form of Indemnification Agreement entered into by and between Sensei Biotherapeutics, Inc. and each director and executive officer (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.5	Independent Contractor and Strategic Advisory Services Agreement entered into by and between Sensei Biotherapeutics, Inc. and Samuel Broder M.D., dated as of May 8, 2018, as amended on April 5, 2020 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.6	Lease Agreement, by and between Sensei Biotherapeutics, Inc. and Are-Maryland No. 8 Corp., dated as of October 22, 2020 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.7#	Sensei Biotherapeutics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.8#	Amended and Restated Employment Agreement, by and between Sensei Biotherapeutics, Inc. and John Celebi, dated as of January 28, 2021 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.9#	Amended and Restated Employment Agreement, by and between Sensei Biotherapeutics, Inc. and Marie-Louise Fjaellskog, dated as of January 28, 2021 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.10#	Amended and Restated Employment Agreement, by and between Sensei Biotherapeutics, Inc. and Robert H. Pierce, dated as of January 28, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.11#	Amended and Restated Employment Agreement, by and between Sensei Biotherapeutics, Inc. and Anupama Hoey, dated as of January 28, 2021 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
10.12*#	Non-Employee Director Compensation Policy.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-252138)).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
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 Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

** This certification is being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are 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 Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\+ Portions of this exhibit (indicated by asterisks) have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm if publicly disclosed.

^ Pursuant to Item 601(b)(2) of Regulation S-K, the schedules and exhibits to this agreement are omitted, but will be furnished to the Securities and Exchange Commission upon request.

\# Indicates management contract or compensatory plan.

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**.**

Sensei Biotherapeutics, Inc.

Date: March 30, 2021 By: /s/ John Celebi

John Celebi
President and Chief Executive Officer

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/ John Celebi **John Celebi**	President, Chief Executive Officer and Director (*Principal Executive Officer*)	March 30, 2021
/s/ Erin Colgan **Erin Colgan**	Senior Vice President of Finance and Administration (*Principal Financial and Accounting Officer)*	March 30, 2021
/s/ Bob Holmen **Bob Holmen**	Director	March 30, 2021
/s/ James Peyer, Ph.D. **James Peyer, Ph.D.**	Director	March 30, 2021
/s/ Samuel Broder, M.D. **Samuel Broder, M.D.**	Director	March 30, 2021
/s/ Thomas Ricks **Thomas Ricks**	Director	March 30, 2021
/s/ Deneen Vojta **Deneen Vojta**	Director	March 30, 2021

SENSEI BIOTHERAPEUTICS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Sensei Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sensei Biotherapeutics, Inc. and subsidiary (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, convertible preferred stock, common stock and stockholders' deficit, and cash flows, for each of the 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 as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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/ Deloitte & Touche LLP

Baltimore, Maryland

March 30, 2021

We have served as the Company's auditor since 2016.

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 16,596	$ 251
Deferred offering costs	2,105	—
Prepaid expenses	1,375	251
Total current assets	20,076	502
Property and equipment, net	1,266	268
Deposits	86	447
Total assets	$ 21,428	$ 1,217
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued liabilities	$ 3,882	$ 3,547
Current portion of long-term debt, $6,187 with related parties as December 31, 2019	—	16,055
Accrued interest, including $323 with related parties as of December 31, 2019	—	1,398
Other liabilities	948	714
Total current liabilities	4,830	21,714
Debt	567	—
Other non-current liabilities	138	620
Total liabilities	5,535	22,334
Commitments and contingencies (Note 7)		
Convertible preferred stock (Series A-F), $0.0001 par value; no shares authorized, issued or outstanding at December 31, 2020; 20,000,000 shares authorized, 15,257,663 issued and outstanding at December 31, 2019	—	47,545
Convertible preferred stock (Series AA), $0.0001 par value; 870,211,737 shares authorized, 747,683,172 issued and outstanding at December 31, 2020; liquidation value of $61,411 thousand at December 31, 2020; no shares authorized, issued or outstanding at December 31, 2019	61,411	—
Convertible preferred stock (Series BB), $0.0001 par value; 870,211,737 shares authorized, 52,680,306 issued and outstanding at December 31, 2020; liquidation value of $10,925 thousand at December 31, 2020; no shares authorized, issued or outstanding at December 31, 2019	10,925	—
Stockholders' deficit:		
Common stock, $0.0001 par value; 1,230,000,000 shares authorized as of December 31, 2020, 1,875,422 shares and 369,491 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	55,969	23,650
Accumulated deficit	(112,412)	(92,312)
Total stockholders' deficit	(56,443)	(68,662)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 21,428	$ 1,217

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

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 11,185	$ 8,350
General and administrative	7,528	4,085
Alvaxa IPR&D	738	—
Total operating expenses	19,451	12,435
Loss from operations	(19,451)	(12,435)
Other expense:		
Interest expense, including $645 and $320 with related parties in 2020 and 2019, respectively	(1,689)	(2,256)
Fair value adjustments on embedded debt derivatives, including $575 and $1,070 with related parties in 2020 and 2019, respectively	995	(1,973)
Gain (loss) on debt extinguishment	45	(75)
Other (expense) income, net	—	(1)
Net loss	(20,100)	(16,740)
Cumulative dividends on convertible preferred stock	(104)	(3,804)
Net loss attributable to common stockholders	(20,204)	(20,544)
Net loss per common share, basic and diluted	$ (12.53)	$ (55.92)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	1,612,140	367,359

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

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK, COMMON STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)

	Convertible Preferred Stock (Series A-F)		Convertible Preferred Stock (Series AA)		Convertible Preferred Stock (Series BB)		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at January 1, 2019	15,257,663	$ 47,545	—	$ —	—	$ —	367,213	$ —	$ 22,092	$ (75,572)	$ (53,480)
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,176	—	1,176
Exercise of common stock warrants	—	—	—	—	—	—	2,278		154		154
Issuance of common stock warrants	—	—	—	—	—	—	—	—	228	—	228
Net loss	—	—	—	—	—	—		—	—	(16,740)	(16,740)
Balance at December 31, 2019	15,257,663	$ 47,545	—	$ —	—	$ —	369,491	$ —	$ 23,650	$ (92,312)	$ (68,662)
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,492	—	1,492
Conversion of series A,B,C,D,E,F preferred stock into common stock	(15,257,663)	(47,545)	—	—	—	—	627,871	—	47,545	—	47,545
Conversion of common stock into series AA preferred stock	—	—	210,310,025	17,274	—	—	(148,732)	—	(17,274)	—	(17,274)
Preferred stock issued in exchange for note redemption	—	—	219,764,872	18,050	—	—	—	—	—	—	—
Issuance of series AA preferred stock	—	—	317,608,275	26,087	—	—	—	—	—	—	—
Issuance of series BB preferred stock					52,680,306	10,925					
Issuance of common stock	—	—	—	—	—	—	705,750	—	—	—	—
Exercise of options into common stock	—	—	—	—	—	—	16,666	—	15	—	15
Issuance of common stock related to Alvaxa IPR&D acquisition	—	—	—	—	—	—	304,376	—	541	—	541
Net loss	—	—	—	—	—	—	-	—	—	(20,100)	(20,100)
Balance at December 31, 2020	—	$ —	747,683,172	$ 61,411	52,680,306	$ 10,925	1,875,422	$ —	$ 55,969	$ (112,412)	$ (56,443)

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

SENSEI BIOTHERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2020	2019
Operating activities		
Net loss	$ (20,100)	$ (16,740)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,492	1,176
Depreciation and amortization	209	73
Accretion on debt	1,578	1,394
Fair value adjustments on embedded debt derivatives	(995)	1,973
Interest on capital lease	12	9
Issuance of common stock for Alvaxa acquisition	541	—
(Gain) loss on debt extinguishment	(45)	75
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,124)	377
Deposits	361	—
Accounts payable and accrued liabilities	335	1,659
Accrued interest	53	894
Other liabilities	(22)	539
Net cash used in operating activities	(17,705)	(8,571)
Investing activities		
Purchases of property and equipment	(1,206)	(53)
Alvaxa IPR&D acquisition	(197)	—
Net cash used in investing activities	(1,403)	(53)
Financing activities		
Proceeds from the PPP loan	567	—
Proceeds from the exercise of common stock warrants and options	20	154
Deferred offering costs	(2,105)	—
Capital lease payments	(41)	(27)
Proceeds on the issuance of series AA convertible preferred stock	26,087	—
Proceeds on the issuance of series BB convertible preferred stock	10,925	—
Proceeds on the issuance of debt, including $3,750 with related parties in 2019	—	8,095
Net cash provided by financing activities	35,453	8,222
Net increase (decrease) in cash and cash equivalents	16,345	(402)
Cash and cash equivalents at beginning of period	251	653
Cash and cash equivalents at end of period	$ 16,596	$ 251
Supplemental disclosure of noncash financing information:		
Capital equipment	$ —	$ 166
Property and equipment additions included in accounts payable and accrued liabilities	$ 204	$ —
Deferred offering costs included in accounts payable and accrued liabilities	$ 1,207	$ —
Interest on financing	$ 12	$ 9
Conversion of series A,B,C,D,E,F convertible preferred stock into common stock	$ 47,545	$ —
Conversion of common stock into series AA convertible preferred stock	$ 17,274	$ —
Convertible preferred stock issued in exchange for note redemption	$ 18,050	$ —

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

1. ORGANIZATION AND OPERATIONS

Business

Sensei Biotherapeutics, Inc. (the "Company" or "Sensei") is a clinical-stage immunotherapy company that was incorporated in 1999 as a Maryland corporation until incorporated in Delaware on December 1, 2017. The Company is engaged in the discovery and development of next generation therapies with an initial focus on treatments for cancer.

On May 18, 2020, the Company acquired Alvaxa Biosciences, Inc. ("Alvaxa") in a cash and stock purchase ("Stock Purchase Agreement"). Under the terms of the Stock Purchase Agreement, the Company acquired Alvaxa's existing camelid nanobodies and other biomaterials ("Biomaterials"), expertise in nanobody discovery, as well as a license agreement with a research organization. The former majority shareholder of Alvaxa is the Company's current Chief Scientific Officer. Under the Stock Purchase Agreement, the Company paid $197 thousand to settle liabilities assumed from Alvaxa and issued 304,376 shares of the Company's common stock to the shareholders of Alvaxa. The Company has evaluated the acquisition under ASC 805, *Business Combinations* and determined this transaction to be an asset acquisition.

The 304,376 shares of common stock was valued at $541 thousand in total, based on a valuation determined with the assistance of a third party. The Company determined that substantially all the value acquired in the transaction related to the Biomaterials and represents in-process research and development ("IPR&D"). The liabilities of $197 thousand assumed were related to previously incurred employee costs as well as contractually required vendor payments. The consideration transferred in this transaction was recorded as an expense in the Alvaxa IPR&D line item within the Statement of Operations during the year ended December 31, 2020.

Liquidity and capital resources

Since its inception, the Company has devoted substantially all of its resources to advancing development of its portfolio of programs, establishing and protecting its intellectual property, conducting research and development activities, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Since its inception, the Company has incurred substantial losses and had a net loss of $20.1 million for the year ended December 31, 2020. As of December 31, 2020, the Company had an accumulated deficit of $112.4 million. The Company expects to generate operating losses and negative operating cash flows for the foreseeable future.

On February 3, 2021, the Company completed its initial public offering, or IPO, in which the Company issued and sold 8,030,295 shares of its common stock, including 1,030,243 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $19.00 per share, for aggregate gross proceeds of $152.6 million. The Company received $138.5 million in net proceeds after deducting underwriting discounts and estimated offering expenses payable by the Company.

The Company expects that its cash and cash equivalents as of December 31, 2020 of $16.6 million, along with $138.5 million in net proceeds from its initial public offering, will be sufficient to fund its operations for at least the next twelve months from the date of issuance of these financial statements. The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to raise capital as and when needed would have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying consolidated financial statements in conformity with generally accepted accounting principles in the United States ("US GAAP"). The consolidated financial statements include those accounts of the Company and its subsidiaries after elimination of all intercompany accounts and transactions.

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods presented. Estimates are used for, but are not limited to, depreciation of equipment, the Company's enterprise value, fair value of financial instruments, the Company's ability to continue as a going concern and contingencies. Actual results may differ from those estimates.

Cash and Cash Equivalents

Cash equivalents are highly liquid investments with an original maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions.

Deferred Offering Costs

The Company capitalizes as prepaid expenses certain legal, professional accounting and other third-party fees that are directly associated with preferred stock or common stock financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of additional paid-in capital generated as a result of the offering.

Concentrations of Credit Risk and Off-Balance Sheet Risk

The Company maintains its cash in bank deposit and checking accounts that at times exceed insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized over the estimated useful lives of the assets. Repairs or maintenance costs are expensed as incurred. Depreciation is computed using the straight-line method over the following estimated useful lives:

Office equipment and furniture	3—7 years
Research equipment	1—7 years
Capital lease	Lesser of the asset life or lease term

Fair Value of Financial Instruments

US GAAP requires disclosure of fair value information about financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. The framework provides a fair value hierarchy that prioritizes the inputs for the valuation techniques. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements) and minimizes the use of unobservable inputs. The most observable inputs are used, when available. The three levels of the fair value hierarchy are described as follows:

Level 1—Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2—Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability; and inputs that are derived from, or corroborated by, observable market data by correlation or other means.

Level 3—Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Classification of Convertible Preferred Stock

The Company classifies convertible preferred stock outside of stockholders' deficit on its balance sheets as the requirements of triggering a deemed liquidation event are not within the Company's control. In the event of a deemed liquidation event, the proceeds from the event are distributed in accordance with liquidation preferences (Note 8). The Company adjusts the carrying value of the convertible preferred stock to their redemption values when it becomes probable a redemption event will occur.

Research and Development

Research and development costs are expensed in the period incurred. Research and development costs include payroll and personnel expense; consulting costs; external contract research and development costs; raw materials and allocated overhead such as depreciation and amortization, rent and utilities. Advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and are expensed over the service period as the services are provided or when the goods are consumed.

Clinical trial costs are a component of research and development expenses. The Company estimates expenses incurred for clinical trials that are in process based on services performed under contractual agreements with clinical research organizations and actual clinical investigators. Included in the estimates are (1) the fee per patient enrolled as specified in the clinical trial contract with each institution participating in the clinical trial and (2) progressive data on patient enrollments obtained from participating clinical trial sites and the actual services performed. Changes in clinical trial assumptions, such as the length of time estimated to enroll all patients, rate of screening failures, patient drop-out rates, number and nature of adverse event reports, and the total number of patients enrolled can impact the average and expected cost per patient and the overall cost of the clinical trial. The Company monitors the progress of the trials and their related activities and adjusts, when applicable, the accruals accordingly. Adjustments to accruals are charged to expense in the period in which the facts that give rise to the adjustment become known. In the event of early termination of a clinical trial or site, the Company would accrue an amount based on estimates of the remaining noncancellable obligations associated with winding down the clinical trial or cancelation of a participating site.

Stock-Based Compensation

The Company accounts for all stock-based compensation, including stock options and warrants, at fair value and recognizes stock-based compensation expense for those equity awards, net of actual forfeitures, over the requisite service period, which is generally the vesting period of the respective award.

The fair value of the Company's stock options and warrants on the date of grant was determined by the Company with the assistance of a third-party valuation specialist in accordance with the guidance in the American Institute of Certified Public Accountants Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, as the Company's common stock was not actively traded prior to February 3, 2021.

Income Taxes

Income taxes are accounted for using the asset and liability method of accounting for taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases, including operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is established when necessary to reduce net deferred tax assets to the amount expected to be realized through future operations. Income tax expense consists of taxes payable for the current period and the net change during the period in deferred tax assets and liabilities.

The Company evaluates its uncertain tax positions based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized. Potential interest and penalties associated with any uncertain tax positions are recorded as a component of income tax expense. Management has evaluated the Company's tax position and concluded that the Company has taken no uncertain tax positions that would require adjustment or disclosure in the consolidated financial statements.

Net Loss Per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated, and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common stock. For purpose of this calculation, outstanding stock options, stock warrants and convertible preferred stock are considered potential dilutive common stock and are excluded from the computation of net loss per share as their effect is anti-dilutive.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to be outstanding if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2020 and 2019.

Comprehensive Loss

There were no differences between net loss and comprehensive loss presented in the consolidated statements of operations for 2020 and 2019.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

Reclassifications

Certain reclassifications have been made to the presentation of amounts in the consolidated balance sheet and consolidated statement of cash flows as of and for the year ended December 31, 2019 to conform to the current year presentation related to accounts payable and accrued liabilities and other current liabilities.

Emerging Growth Company Status

The Company is an "emerging growth company," ("EGC") as defined in the Jumpstart Our Business Startups Act, (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has elected to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's financial statements may not be comparable to companies that comply with public company Financial Accounting Standards Board ("FASB") standards' effective dates. The Company may take advantage of these exemptions up until the earliest of (i) December 31, 2026, (ii) the last day of the fiscal year in which it has total annual gross revenues of $1.07 billion or more, (iii) the date on which it has issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which it is deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission ("SEC"), which generally is when it has more than $700 million in market value of its stock held by non-affiliates as of the prior June 30th.

Recently Issued Accounting Standards

In February 2016, the FASB issued Accounting Standards Updates ("ASU") No. 2016-02, *Leases (Topic 842)*, as amended, with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize the liabilities related to all

leases, including operating leases on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This update is effective for entities other than public business entities, including emerging growth companies that elected to defer compliance with new or revised financial accounting standards until a company that is not an issuer is required to comply with such standards, for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the impact of adopting ASU No. 2016-02 on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326)*. ASU No. 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU No. 2016-13 within ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. This update is effective for entities other than public business entities, including emerging growth companies that elected to defer compliance with new or revised financial accounting standards until a company that is not an issuer is required to comply with such standards, for annual reporting periods beginning after December 15, 2022.The Company is currently evaluating the impact that ASU No. 2016-13 will have on the consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement* (*Topic 820*), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. This update removed the following disclosure requirements: (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels; and (3) the valuation processes for Level 3 fair value measurements. Additionally, this update added the following disclosure requirements: (1) the changes in unrealized gains and losses for the period included in other comprehensive income and loss for recurring Level 3 fair value measurements held at the end of the reporting period; (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. The Company adopted ASU No. 2018-13 on January 1, 2020 and it did not have a material effect on the consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*. ASU No. 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This update is effective for entities other than public business entities, including emerging growth companies that elected to defer compliance with new or revised financial accounting standards until a company that is not an issuer is required to comply with such standards, for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. The Company is currently evaluating the impact that ASU No. 2019-12 will have on the consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*. This update simplifies the accounting for convertible debt instruments by removing certain accounting separation models as well as the accounting for debt instruments with embedded conversion features that are not required to be accounted for as derivative instruments. The update also updates and improves the consistency of earnings per share calculations for convertible instruments. The amendments in this ASU are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company is currently evaluating the impact that the implementation of this update will have on the Company's consolidated financial statements and related disclosures.

3. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Office equipment and furniture	$ 94	$ 14
Research equipment	1,767	641
Total property and equipment	1,861	655
Less accumulated depreciation and amortization	(595)	(387)
Property and equipment, net	$ 1,266	$ 268

Depreciation and amortization expense for the years ended December 31, 2020 and 2019 was $209 thousand and $73 thousand, respectively.

4. OTHER CURRENT LIABILITIES

Other current liabilities consist of the following (in thousands):

	December 31, 2020	December 31, 2019
Compensation and benefits	$ 916	$ 685
Other	32	29
Total other current liabilities	$ 948	$ 714

5. DEBT

Debt consists of the following (in thousands):

	December 31, 2020	December 31, 2019
PPP Loan	$ 567	$ —
2019 Notes	—	2,345
2019 Secured Notes (related party)	—	3,854
2019 Bridge Note	—	1,000
2019 Special Note (related party in 2020)	—	2,570
2018 Bridge Notes (related party)	—	3,000
2017 Notes	—	4,050
Discounts	—	(764)
Total debt	567	16,055
Less current portion	—	(16,055)
Noncurrent debt	$ 567	$ —

As of December 31, 2020, the remaining debt is presented as a non-current liability in the Company's consolidated balance sheet.

PPP loan

In May 2020, the Company received $567 thousand in loan funding from the Paycheck Protection Program ("PPP") pursuant to the Coronavirus Aid, Relief, and Economic Security Act, as amended by the Flexibility Act, and administered by the Small Business Administration. The unsecured loan (the "PPP Loan") is with Silicon Valley Bank.

Under the terms of the PPP Loan, interest accrues on the outstanding principal at a rate of 1.0% per annum. The term of the PPP Loan is two years, though it may be payable sooner in connection with an event of default under the PPP Loan. To the extent the PPP Loan amount is not forgiven under the PPP, the Company is obligated to make equal monthly payments of principal and interest, beginning after determination of forgiveness by the lender. If the Company applies for forgiveness before August 2021 and forgiveness is not granted, principal and interest payments will be required beginning in May 2022. If the Company does not apply for loan forgiveness by August 2021, principal and interest will be required beginning in August 2021.

2019 Notes

During the period from April 2019 through September 2019, the Company issued $2,345 thousand of convertible promissory notes ("2019 Notes"). Interest on the principal amount outstanding is fixed at 10% with a one-year maturity date, if not previously converted to shares of the Company's equity securities. The 2019 Notes were redeemed in January 2020 as part of the Company's recapitalization disclosed in Note 8.

The 2019 Notes include detachable warrants to purchase 7,313 of the Company's common stock at exercise prices between $64.80 and $122.88 per share. The detachable warrants have an expiration date of ten years from the issuance date, or fiscal year 2029. The estimated fair value of the detachable warrants was determined using the Black-Scholes option-pricing model (Level 3

hierarchy) and totaled $51 thousand upon issuance. The fair value of the detachable warrants was treated as a discount on the 2019 Notes and amortized as incremental interest expense using the effective interest method over the life of the 2019 Notes.

2019 Secured Notes (Related Party)

In September and October 2019, the Company issued an aggregate of $1,500 thousand in secured convertible promissory notes ("2019 Secured Notes") with a repayment premium of 150% of the principal amount. Interest on the principal amount outstanding is fixed at 10% with a maturity date of December 31, 2020. The repayment premium of $2,250 thousand was being amortized as incremental interest expense using the effective interest method over the life of the 2019 Secured Notes. The 2019 Secured Notes were redeemed in January 2020 as part of the Company's recapitalization disclosed in Note 8.

The automatic conversion features of the 2019 Secured Notes were determined by management to be embedded derivative instruments. The embedded derivative instruments are initially measured at fair value and classified as a liability on the balance sheet, within the same line item as the 2019 Secured Notes. Subsequent changes in fair value are in net loss on the consolidated statement of operations as fair value adjustments on embedded debt derivatives expense. To determine the fair value of the aggregated automatic conversion features, management utilized a "with-and-without" in a modified convertible bond model, incorporating the automatic conversion features. Key assumptions utilized in determining the initial fair value were: (a) 5% to 10% probability of settlement at the contractual maturity date; (b) 25% probability of settlement on a change of control or upon a qualified initial public offering in 9 to 10 months of issuance; and (c) 65% probability of settlement on a qualified financing in 6 months of issuance. Based upon the modified convertible bond model utilized by management, the fair value of the automatic conversion features was determined to be $940 thousand upon issuance of the 2019 Secured Notes and is being amortized as incremental interest expense using the effective interest method over the life of the 2019 Secured Notes.

2019 Bridge Note

In November 2019, the Company issued a $1,000 thousand bridge convertible promissory note ("2019 Bridge Note"). Interest on the principal amount is fixed at 7% and commences 60 days after the issuance date with a maturity date of December 31, 2020. The 2019 Bridge Note was redeemed in January 2020 as part of the Company's recapitalization disclosed in Note 8.

2019 Special Note

In April 2019, the Company issued a $1,000 thousand convertible promissory note ("2019 Special Note"). Interest on the principal amount outstanding is fixed at 10% with a one-year maturity date, if not previously converted to shares of the Company's equity securities.

The 2019 Special Note contains a feature requiring amendment of the original instrument if the Company issues additional instruments with preferable terms relative to those contained in the 2019 Special Note. In September 2019, the original agreement was amended requiring a 150% repayment premium in addition to the original 10% interest rate based upon the Company's issuance of the 2019 Secured Notes. The contractual amendment was treated as a debt extinguishment and a loss of $75 thousand was recorded in net loss on the consolidated statement of operations as a loss on extinguishment expense. The repayment premium of $1,500 thousand is being amortized as incremental interest expense using the effective interest method over the life of the 2019 Special Note.

The automatic conversion features of the 2019 Special Note were determined by management to be embedded derivative instruments. The embedded derivative instruments are initially measured at fair value and classified as a liability on the balance sheet, within the same line item as the 2019 Special Note. Subsequent changes in fair value are in net loss as fair value adjustments on embedded debt derivatives expense. To determine the fair value of the aggregated automatic conversion features, management utilized a "with-and-without" in a modified convertible bond model, incorporating the automatic conversion features. Key assumptions utilized in determining the initial fair value were: (a) 10% probability of settlement at the contractual maturity date; (b) 25% probability of settlement on a change of control or upon a qualified initial public offering in 10 months of issuance; and (c) 65% probability of settlement on a qualified financing in 6 months of issuance. Based upon the modified convertible bond model utilized by management, the fair value of the automatic conversion features was determined to be $663 thousand upon issuance of the 2019 Special Note and is being amortized as incremental interest expense using the effective interest method over the life of the 2019 Special Note.

The 2019 Special Note includes a detachable warrant allowing the purchase of 3,886 of the Company's common stock at an exercise price of $64.32 per share. The detachable warrant has an expiration date of ten years from the issuance date, or fiscal year 2029. The fair value of the detachable warrant was treated as a discount on the 2019 Special Note and amortized as incremental interest expense using the effective interest method over the life of the 2019 Special Note. The estimated fair value of the detachable warrant was determined using the Black-Scholes option-pricing model (Level 3 hierarchy) and totaled $74 thousand upon issuance.

On March 27, 2020, the Company consented to the exchange of the 2019 Special Note where the original holder of the 2019 Special Note sold it to a current equity owner of the Company. The detachable warrant issued in conjunction with the 2019 Special Note for 3,886 common stock was not included in the exchange and was subsequently canceled.

The 2019 Special Note matured in April 2020 and stopped accruing interest at that time. Management determined the fair value of the conversion features within the 2019 Special Note was zero as of September 30, 2020 since the 2019 Special Note had matured, and the conversion features provided no incremental value to the holder beyond the contractually obligated amount. In November 2020, the 2019 Special Note, repayment premium and accrued interest was redeemed into 31,591,824 shares of Series AA convertible preferred stock. The delay from maturity in April 2020 to redemption in November 2020 was administrative in nature, as the holder is a principle owner related party.

2018 Bridge Notes (Related Party)

The Company issued $2,250 thousand and $750 thousand 2018 convertible promissory notes ("2018 Bridge Notes") in 2019 and 2018, respectively, to fund the Company's operations. Interest on the principal amount outstanding is fixed at 10%. The 2018 Bridge Notes were redeemed in January 2020 as part of the Company's recapitalization disclosed in Note 8.

The 2018 Bridge Notes include detachable warrants to purchase 11,718 and 3,906 shares issued in 2019 and 2018, respectively, of the Company's common stock at an exercise price of $122.88 per share. The detachable warrants expire on December 19, 2028. The estimated fair value of the detachable warrants was determined using the Black-Scholes option-pricing model (Level 3 hierarchy), treated as a discount on the 2018 Bridge Notes and amortized as incremental interest expense using the effective interest method over the life of the 2018 Bridge Notes.

2017 Notes

The Company issued $4,050 thousand convertible promissory notes in 2017 ("2017 Notes") in exchange for cash of the same amount. Interest on the principal amount outstanding is fixed at 8%. The 2017 Notes were redeemed in January 2020 as part of the Company's recapitalization disclosed in Note 8.

6. FAIR VALUE MEASUREMENTS

The Company did not have any financial liabilities measured at fair value on a recurring basis as of December 31, 2020. The following table presents information about the Company's financial liabilities measured at fair value on a recurring basis as of December 31, 2019 and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2019			
	Level 1	Level 2	Level 3	Total
Current liabilities				
Embedded debt derivatives	$ —	$ —	$ 3,920	$ 3,920
Total liabilities measured at fair value	$ —	$ —	$ 3,920	$ 3,920

The Company's embedded debt derivatives are measured at fair value using a probability-weighted discounted cash flow valuation methodology. The determination of the fair value of embedded debt derivatives includes inputs not observable in the market and as such, represents a Level 3 measurement. The methodology utilized requires inputs based on certain subjective assumptions, including probabilities of debt settlement scenarios and a discount rate. This approach results in the classification of these embedded debt derivatives as Level 3 of the fair value hierarchy.

The assumptions utilized to value the embedded debt derivatives during the year ended December 31, 2020 prior to the settlement of such instruments included the actual outcome of the underling debt host contract, whether it was settled on a qualified financing prior to the contractual maturity date or settlement at the contractual maturity date. For the year ended December 31, 2020, the Company recognized $1.0 million of income in the statement of operations as other income—fair value adjustments on embedded debt derivatives.

The assumptions utilized to value the embedded debt derivatives at December 31, 2019 were the probability of (a) 3% probability of settlement at the contractual maturity date; (b) 5% probability of settlement on a change of control or upon a qualified initial public offering prior to the contractual maturity date; and (c) 92% probability of settlement on a qualified financing prior to the contractual maturity date. For the year ended December 31, 2019, the Company recognized a $2.0 million expense in the statement of operations as other expense—fair value adjustments on embedded debt derivatives.

The following table provides a reconciliation of embedded debt derivatives measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Amount
Balance at January 1, 2019	$ —
Additions	1,947
Change in fair value	1,973
Balance at December 31, 2019	$ 3,920
Change in fair value	(995)
Settlement	(2,925)
Balance at December 31, 2020	$ —

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2020 and 2019.

7. COMMITMENTS AND CONTINGENCIES

Operating Lease

As of December 31, 2020, the Company leases an office facility and other equipment under operating leases, which expire at various dates through 2027. Lease expense for the years ended December 31, 2020 and 2019 was $1,439 thousand and $1,107 thousand, respectively.

The following table presents the future annual minimum payments required under noncancellable operating leases at December 31, (in thousands):

2021	$ 427
2022	314
2023	323
2024	328
2025	337
2026	347
2027	59
Total operating lease obligations	$ 2,135

Capital Lease

The Company leases research equipment under a capital finance lease. The capital lease asset is classified within property and equipment, net within the Company’s consolidated balance sheets.

The following table presents the future annual minimum payments under the capitalized lease, together with the present value of net minimum lease payments at December 31, (in thousands):

2021	$ 41
2022	41
2023	41
2024	14
Total capital lease obligations	137
Less amount representing interest	(19)
Present value of minimum capital lease obligations	$ 118

License Agreements

In the normal course of business, the Company enters into licensing agreements with various parties to obtain the right to make, use, and sell licensed products currently in development.

Litigation

The Company records estimated losses from loss contingencies, such as a loss arising from a litigation, when it determines that it is probable a liability has been incurred and the amount of loss can be reasonably estimated. Litigation is subject to many factors that are difficult to predict so that there can be no assurance, in the event of a material unfavorable result in one or more claims, the Company will not incur material costs.

During 2017, the Company became actively involved in a matter pending in the Ontario (Canada) Superior Court of Justice which names, among multiple other defendants, the Company and two former officers of the Company. The claims pending in this matter allege breach of contract by the Company and seek declaratory and other relief, including monetary damages from the Company, and the individual defendants, including the Company's former officers. The claims by such plaintiffs were originally made in a lawsuit filed in Ontario during October 2011, but was not pursued by such plaintiffs in any material manner until 2017. The Company believes that there is no merit to the claims alleged against the Company and its former officers, including no alleged breach of contract by the Company, and intends to vigorously defend against the claims pertaining to the Company and its former officers. At the present stage of the suit, management believes the outcome in this matter is not likely to have any material impact on the Company's results, cash flows, or financial position.

Coronavirus pandemic

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID- 19 outbreak as a pandemic, based on the rapid increase in exposure globally. The full impact of the COVID-19 outbreak continues to evolve as of the date of these financial statements. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company's financial condition, liquidity, and future results of operations. Management is actively monitoring the global situation on its financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity. Although the Company cannot estimate the length or gravity of the impact of the COVID-19 outbreak at this time, if the pandemic continues, it may have a material adverse effect on the Company's results of future operations, financial position, and liquidity in 2021.

8. EQUITY

January Recapitalization

In January 2020, the Company entered into an agreement with a third party, who is the holder of the 2019 Bridge Note, and the majority of the Company's convertible preferred stock series A through F holders ("Majority Legacy Preferred Stockholders") that provided a new source of capital and restructured the Company's existing capital structure (the "Recapitalization"). The third party invested $4 million in exchange for 48,700,311 shares of Series AA convertible preferred stock and a warrant to purchase 634,118 shares of the Company's common stock at an exercise price of $0.01 per share. The warrant was subsequently exercised in January 2020. Additionally, the agreement with the Majority Legacy Preferred Stockholders caused all other holders of convertible preferred stock series A through F holders ("Minority Legacy Preferred Stockholders") and the Majority Legacy Preferred Stockholders to receive 30,140,432 shares of the Company's common stock ("Newly Issued Common Stock") in exchange for their holdings of the Company's convertible preferred stock series A through F, including cumulative and unpaid dividends, as part of the Recapitalization.

The Majority Legacy Preferred Stockholders agreed to invest additional capital into the Company in exchange for Series AA convertible preferred stock. Minority Legacy Preferred Stockholders were provided the opportunity to invest additional capital into the Company in exchange for Series AA convertible preferred stock. All Majority and Minority Legacy Preferred Stockholders who invested additional capital into the Company during January 2020 were allowed to convert their Newly Issued Common Stock into Series AA convertible preferred stock at a conversion rate based upon their incremental and historical investment into the Company. The Majority and Minority Legacy Preferred Stockholders invested $6.6 million in exchange for 79,954,952 shares of Series AA convertible preferred stock. The Majority and Minority Legacy Preferred Stockholders also exchanged 148,732 shares of Newly Issued Common Stock for 210,310,025 shares of Series AA convertible preferred stock under the Recapitalization agreement.

The Company's issuance of Series AA convertible preferred stock triggered the redemption of the 2019 Notes, 2019 Secured Notes, 2019 Bridge Note, 2018 Bridge Notes, and 2017 Notes, as well as accrued and unpaid interest and repayment premium on the 2019 Secured Notes, into shares of Series AA convertible preferred stock. These debt instruments were redeemed for 188,173,050 shares of the Series AA convertible preferred stock, which resulted in a gain on debt extinguishment of $45 thousand.

The Company amended and restated its certificate of incorporation as part of the Recapitalization authorizing a total number of common stock and preferred stock of 1,230,000,000 and 870,211,737 respectively, with a par value of $0.0001 for each share.

Secondary Series AA Convertible Preferred Stock Issuance

From July to September 2020, the Company issued and sold 103,453,773 shares of Series AA convertible preferred stock at $0.082135 per share in exchange for $8.5 million in gross proceeds.

Series BB Convertible Preferred Stock Issuance

In December 2020, the Company issued and sold 52,680,306 shares of Series BB convertible preferred stock at $0.207383 per share in exchange for $10.9 million in gross proceeds.

Convertible Preferred Stockholder Rights

As described in Note 14 below, in connection with the Company's initial public offering, all outstanding shares of convertible preferred stock converted into shares of the Company's common stock. A summary of the more significant rights and preferences of the Series AA convertible preferred stock and Series BB convertible preferred stock as of December 31, 2020 are as follows:

Dividend Rights

The Company shall not declare, pay, or set aside any dividends on shares of any other class or series of capital stock unless the holders of the convertible preferred stock then outstanding shall first receive a dividend at the rate of 8% of the original issue price, subject to adjustment for stock dividend, stock split, combination or other similar recapitalization. The Company has not declared or paid any dividends.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, the holders of Series BB convertible preferred stock shall be entitled to be paid out of the Company's assets available for distribution to its stockholders before any payment shall be made to holders of Series AA convertible preferred stock or common stock. The entitled amount for Series BB convertible preferred stockholders is the original issue price, subject to adjustment for stock dividend, stock split, combination or other similar recapitalization, plus declared and unpaid dividends.

After payment in full of all Series BB convertible preferred stock in a liquidation event, the holders of Series AA convertible preferred stock shall be entitled to be paid out of the Company's assets available for distribution to its stockholders before any payment shall be made to holders of common stock. The entitled amount for Series AA convertible preferred stockholders is the original issue price, subject to adjustment for stock dividend, stock split, combination or other similar recapitalization, plus declared and unpaid dividends.

After the payment in full of the Series BB convertible preferred stock and Series AA convertible preferred stock, the remaining Company assets, shall be distributed among the holders of the shares of Series BB convertible preferred stock, Series AA convertible preferred stock and common stock, pro rata based on the number of shares held by each holder, as if the convertible preferred stock had been converted to common stock prior to liquidation.

A merger or consolidation of substantially all or a significant portion of the Company's assets shall be considered a deemed liquidation event unless the holders of at least two-thirds of the outstanding shares of Series AA convertible preferred stock and Series BB convertible preferred stock, voting together as a single class on an as-converted to common stock basis, elect otherwise by written notice sent to the Company.

Voting Rights

Holders of outstanding shares of Series AA convertible preferred stock and Series BB convertible preferred stock shall be entitled to cast the number of votes equal to the number of shares of common an as-converted to basis and vote together with the holders of common stock as a single class.

Conversion Rights

Each share of Series AA convertible preferred stock and Series BB convertible preferred stock shall be convertible, at the option of the holder, into shares of common stock. The conversion ratio for Series AA convertible preferred stock and Series BB convertible preferred stock is one share of common stock for every 48 shares of convertible preferred stock as a result of the reverse stock split disclosed in Note 14. The conversion ratio is subject to adjustment should specified dilutive events occur. All shares of the Series AA

convertible preferred stock and Series BB convertible preferred stock converted into shares of the Company's common stock closing of the IPO disclosed in Note 14.

Series A, B, C, D, E and F Convertible Preferred Stock

All Series A, B, C, D, E, and F convertible preferred stock were converted into common stock as part of the January Recapitalization discussed above. There were no other transactions involving Series A, B, C, D, E, and F convertible preferred stock during the years ended December 31, 2020 and 2019.

The following is a summary of the Company's Series A, B, C, D, E, and F convertible preferred stock as of December 31, 2019 (in thousands, except for share and par value data):

	Par Value	Outstanding	Value
Series A convertible preferred stock	$ 0.0001	2,035,428	$ 1,425
Series B convertible preferred stock	$ 0.0001	1,809,996	2,715
Series C convertible preferred stock	$ 0.0001	2,156,667	6,470
Series D convertible preferred stock	$ 0.0001	2,969,693	9,800
Series E convertible preferred stock	$ 0.0001	4,285,879	17,135
Series F convertible preferred stock	$ 0.0001	2,000,000	10,000
Total		15,257,663	$ 47,545

Dividends are cumulative and accrue annually on all outstanding Series A, B, C, D, E and F of preferred stock at 8% per annum.

Cumulative and unpaid dividends were converted into shares of common stock at the same rates as the underlying convertible preferred stock as part of the January Recapitalization disclosed above.

The following is a summary of cumulative and unpaid dividends on the Company's convertible preferred stock as of December 31, 2019 (in thousands):

Series A convertible preferred stock	$ 2,173
Series B convertible preferred stock	3,872
Series C convertible preferred stock	8,071
Series D convertible preferred stock	10,965
Series E convertible preferred stock	10,751
Series F convertible preferred stock	2,311
Total	$ 38,143

Common Stock Warrants

During 2020, the Company granted warrants to purchase approximately 1,099,536 shares of the Company's common stock in connection with equity fundraising events. The Company used the Black-Scholes option-pricing model to estimate the grant date fair value of the common stock warrants between $0.60 and $7.49 per share and $1.44 per share on a weighted average basis.

The following is a summary of the common stock warrant activity related to common stock warrants issued in conjunction with equity and debt fundraising events during the years ended December 31, 2020 and 2019:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	3,906	$ 122.88	9.98	$ —
Granted	22,917	$ 99.30		
Exercised	—	$ —		
Expired	—	$ —		
Outstanding at December 31, 2019	26,823	$ 102.74	9.17	$ —
Granted	1,099,536	$ 1.40		
Exercised	(710,211)	$ 0.01		
Expired	(3,886)	$ 64.32		
Outstanding at December 31, 2020	412,262	$ 9.60	6.71	$ 1,380

9. STOCK-BASED COMPENSATION

In 2018, the board of directors approved the Company's 2018 Stock Incentive Plan (the "2018 Plan")—which supersedes and replaces previous incentive stock plans—and reserved 104,167 common shares for issuance under the 2018 Plan. All previously issued and outstanding stock-based awards issued under predecessor incentive plans were adopted into the 2018 Plan. The 2018 Plan provides the issuance of stock awards to attract and retain employees, directors, consultants and advisors and to provide incentive for individuals to contribute to the growth of the Company.

During the year ended December 31, 2020, the Company's 2018 Plan was amended to increase the number of shares of common stock reserved for issuance under the Plan from to 2,552,083 shares in the aggregate. As of December 31, 2020, 600,588 common shares remain available for future awards under the 2018 Plan.

Stock Options

During 2020, the Company granted options to purchase 1,899,507 shares of common stock to employees, consultants, and nonexecutive directors pursuant to the 2018 Plan. The stock options granted during 2020 vest over a period of 6 to 48 months with an exercise price of $1.23 to $6.00 per share. The Company uses the Black-Scholes option-pricing model to estimate the fair value of the stock options on the grant dates between $2.29 and $6.06 per share.

During 2019, the Company granted options to purchase 6,246 shares of common stock to employees, consultants, and nonexecutive directors pursuant to the 2018 Plan. The stock options granted during 2019 vest over a period of 6 to 48 months with an exercise price between $16.32 and $122.88 per share. The Company uses the Black-Scholes option-pricing model to estimate the fair value of the stock options on the grant dates between $0.48 and $2.88 per share.

The following is a summary of the stock option award activity under the 2018 Plan during the years ended December 31, 2020 and 2019:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	80,794	$ 120.73	9.20	$ —
Granted	6,246	$ 42.96		
Exercised	—	$ —		
Forfeited	(8,160)	$ (122.47)		
Expired	(1,276)	$ (116.53)		
Outstanding at December 31, 2019	77,604	$ 114.11	8.12	$ —
Granted	1,899,507	$ 2.02		
Exercised	(16,666)	$ (1.23)		
Forfeited	(13,322)	$ (119.38)		
Expired	—	$ —		
Outstanding at December 31, 2020	1,947,123	$ 5.70	9.56	$ 10,284
Exercisable at December 31, 2020	123,108	$ 49.25	8.52	$ 441
Options expected to vest at December 31, 2020	1,824,015	$ 2.75	9.65	$ 9,843

The aggregate intrinsic value of stock options exercised in the year ended December 31, 2020 was $0.1 million.

The total fair value of options vested during the years ended December 31, 2020 and 2019 was $1.1 million and $1.8 million, respectively.

At December 31, 2020, there was approximately $5.9 million of unrecognized stock-based compensation expense associated with the stock options, which is expected to be recognized over a weighted-average period of 2.99 years.

At December 31, 2019, there was approximately $1.2 million of unrecognized stock-based compensation expense associated with the stock options, which is expected to be recognized over a weighted-average period of 2.26 years.

Common Stock Warrants

During 2019, the Company granted warrants to purchase 208 shares of the Company's common stock to a vendor. The common stock warrants granted during 2019 vested immediately with an exercise price of $122.88 per share. The Company uses the Black-Scholes option-pricing model to estimate the fair value of the awards on the grant date of $10.08 per share.

The following is a summary of the common stock warrant activity during the years ended December 31, 2020 and 2019:

	Number of Common Stock Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	75,120	$ 24.19	2.34	$ 596
Granted	208	$ 122.88		
Exercised	(2,278)	$ (67.51)		
Expired	(15,630)	$ (78.72)		
Outstanding at December 31, 2019	57,420	$ 7.95	4.83	$ —
Granted	—	$ —		
Exercised	—	$ —		
Expired	(208)	$ (96.00)		
Outstanding and exercisable at December 31, 2020	57,212	$ 7.62	3.64	$ 98

As of December 31, 2020, there was no unrecognized stock-based compensation expense associated with the common stock warrants.

During 2020 and 2019, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options and common stock warrants granted. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	Years Ended December 31,	
	2020	2019
Volatility	90%-100%	90.0%
Expected life (years)	0.5–6.1	0.5–10.0
Risk-free interest rate	0.1%–0.7%	1.4%-2.5%
Dividend rate	—%	—%

- Volatility—The Company estimates the expected volatility of its common stock at the date of grant based on the historical volatility of comparable public companies over the expected term.
- Expected life—The expected life is estimated as the contractual term.
- Risk-free interest rate—The risk-free rate for periods within the estimated life of the stock award is based on the U.S. Treasury yield curve in effect at the time of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

Stock-based compensation expense was recorded in the following line items in the consolidated statements of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,	
	2020	2019
Research and development	$ 555	$ 588
General and administrative	937	588
Total stock-based compensation expense	$ 1,492	$ 1,176

10. EMPLOYEE RETIREMENT PLAN

The Company maintains a defined contribution 401(k) profit-sharing plan (the "Plan") for all employees. Under the Plan, participants may make voluntary contributions up to the maximum amount allowable by law. The Plan is based on employees' salary deferral, and the Company matches employees' contributions up to 4% of the employees' base salary. Employees are 100% vested in the Company's match contributions. During the years ended December 31, 2020 and 2019, the Company's matching contributions were $116 thousand and $102 thousand, respectively.

11. RELATED-PARTY TRANSACTIONS

Debt

During 2019, the Company entered into debt arrangements with a principal owner of the Company. These arrangements relate to the 2019 Secured Notes and 2018 Bridge Notes disclosed in Note 5.

During March 2020, a principal owner of the Company purchased the 2019 Special Note directly from the original holder.

Consulting Agreement

During 2020, the Company entered into an agreement with a principal owner of the Company to provide consulting services to the Company in exchange for $1,500 thousand. Under the terms of the agreement, the Company recorded expense of $1,125 thousand in 2020, with payment made in January 2021. The contract was completed and the remaining balance of $375 thousand under the agreement was recorded as an expense in January 2021.

12. INCOME TAXES

Income tax expense consists of the following (in thousands):

	Year Ended December 31,	
	2020	2019
Current:		
Federal	$ —	$ —
State	—	—
Current tax provision	—	—
Deferred:		
Federal	(2,097)	(2,551)
State	(430)	(776)
Deferred tax benefit	(2,527)	(3,327)
Less change in valuation allowance	2,527	3,327
Total income tax provision	$ —	$ —

The effective income tax rate for the years ended December 31, 2020 and 2019 is different from the federal statutory income tax rate primarily due to the change in valuation allowance against deferred tax assets and permanent differences primarily related to non-deductible interest and embedded debt derivatives income and expense. The reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2020	2019
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	3.6	4.6
Non-deductible interest and embedded debt derivative income and expense	(1.7)	(5.4)
Non-deductible transactions costs	(1.2)	—
Other	(0.4)	(0.4)
Equity-based compensation deferred tax asset adjustment	(8.7)	—
Change in valuation allowance	(12.6)	(19.8)
Effective income tax rate	— %	— %

The Company's deferred tax assets consist primarily of its net operating loss and research and development tax credit carryforwards, along with other minor temporary differences. No amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. The Company has provided a valuation allowance against its total net deferred tax assets because the Company's ability to generate sufficient future taxable income is uncertain.

Significant components of the Company's deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2020	2019
Net operating loss carryforwards	$ 22,271	$ 18,338
Equity-based compensation	706	2,384
Research and development tax credit carryforwards	1,364	1,364
Other accruals	414	142
Total deferred tax assets	$ 24,755	22,228
Valuation allowance	(24,755)	(22,228)
Net deferred tax assets	$ —	$ —

The Company has incurred annual net operating losses in each year since inception. The Company believes it could be subject to certain limitations on the utilization of these net operating losses pursuant to Internal Revenue Code Section 382. Therefore, the Company has not reflected the benefit of any such net operating loss carryforwards in the financial statements. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its net deferred tax assets will not be realized, and therefore, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2020 and 2019.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2020 and 2019, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2020 and 2019.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, ("IRC"), a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred as of December 31, 2020. An ownership change would restrict its ability to use its NOLs or tax credit carryforwards and could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

The Company's valuation allowance increased during the year by $2,527 thousand for the year ended December 31, 2020 due primarily to the generation of net operating losses.

As of December 31, 2020, the Company has net operating loss carryforwards for federal and state tax reporting purposes of $81,325 thousand and $79,974 thousand, respectively, a portion of which expire beginning in 2021. Net operating loss carryforwards generated in 2020 and 2019 for federal tax reporting purposes of $16,604 thousand and $10,702 thousand, respectively, have an indefinite life. The remaining federal net operating losses are subject to a 20-year carryforward period. As of December 31, 2020, the Company has research and development tax credit carryforwards of approximately $1,364 thousand, which expire beginning in 2034.

The Company evaluates its uncertain tax positions under ASC 740-10, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. The Company concluded that there are no uncertain tax positions in any of the periods presented.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The earliest tax years that remain subject to examination by jurisdiction is 2017 for both federal and state. However, to the extent the Company utilizes net operating losses from years prior to 2017, the statute remains open to the extent of the net operating losses or other credits are utilized.

13. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Years Ended December 31,	
	2020	2019
Net loss	$ (20,100)	$ (16,740)
Cumulative dividends on convertible preferred stock	(104)	(3,804)
Net loss attributable to common stockholders	$ (20,204)	$ (20,544)
Net loss per share—basic and diluted	$ (12.53)	$ (55.92)
Weighted-average number of shares used in computing net loss per share—basic and diluted	1,612,140	367,359

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Years Ended December 31,	
	2020	2019
Convertible preferred stock	747,683,172	15,257,663
Stock options to purchase common stock	1,947,123	77,604
Warrants issued to employees and contractor to purchase common stock	57,212	57,420
Warrants issued related to convertible notes and other equity agreements	412,262	26,823

14. SUBSEQUENT EVENTS

Reverse stock split

On January 29, 2021, the Company effected a reverse stock split of the Company's common stock on a 48-for-1 basis (the "Reverse Stock Split"). In connection with the Reverse Stock Split, the conversion ratio for the Company's Series AA and Series BB convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. Accordingly, all common stock share and per share amounts, as well as all preferred stock conversion ratios, for all periods presented in these financial statements have been retroactively adjusted, to reflect this reverse stock split and adjustment of the Series AA and BB convertible preferred stock conversion ratios.

Massachusetts operating lease

In January 2021, the Company entered into a new operating lease for general office purposes including laboratory use in Boston, Massachusetts, with a term commencing in May 2021 and continuing through May 2026. The amount of square feet of office space is 10,082 square feet and the Company's minimum commitment under the new lease is approximately $880 thousand dollars annually.

Common stock warrants

In January 2021, the Company issued warrants as a result of the Series AA and Series BB convertible preferred stock raises to an existing principal owner to purchase 1,648,707 shares of common stock with an exercise price of $0.01 per common share. The warrants had a maturity date of 30 days and was exercised in January 2021.

Stock-based compensation

In January 2021, the board of directors approved and granted options to purchase 72,916 shares of the common stock under the 2018 Plan. The awards vest over four years with an exercise price of $9.22 per share.

In February 2021, the board of directors approved and granted options to purchase 1,028,117 shares of the common stock under the 2021 Plan. The awards vest over four years with an exercise price of $19.00 per share.

Series BB convertible preferred stock

In January 2021, the Company issued and sold 113,275,902 shares of Series BB convertible preferred stock at $0.207383 per share in exchange for $23.5 million in gross proceeds.

Initial Public Offering

In February 2021, the Company completed its IPO in which the Company issued and sold 8,030,295 shares of its common stock, including 1,030,243 shares pursuant to the partial exercise of the underwriters' option to purchase additional shares, at a public offering price of $19.00 per share, for aggregate gross proceeds of $152.6 million. The Company received approximately $138.5 million in net proceeds after deducting underwriting discounts and estimated offering expenses payable by the Company. In connection with the IPO, all outstanding shares of convertible preferred stock converted into 19,034,069 shares of the Company's common stock.

DESCRIPTION OF SENSEI BIOTHERAPEUTICS, INC. CAPITAL STOCK

The following description of the common stock of Sensei Biotherapeutics, Inc., or the Company, is a summary and does not purport to be complete. This summary is qualified in its entirety by reference to the provisions of the Delaware General Corporation Law, or the DGCL, and the complete text of the Company's amended and restated certificate of incorporation, or the certificate of incorporation, and amended and restated bylaws or the bylaws, which are incorporated by reference as Exhibits 3.1 and 3.2, respectively of the Company's Annual Report on Form 10-K to which this description is also an exhibit. The Company encourages you to read that law and those documents carefully.

General

Under the certificate of incorporation, our authorized capital stock consists of 250,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock are undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Holders of our common stock are entitled to one vote per share of common stock. Our common stock does not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds.

Liquidation

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

Rights and Preferences

Holders of our common stock have no preemptive rights or other subscription rights and there are no redemption or sinking funds provisions applicable to our common stock. All outstanding shares of our common stock are duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of the certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes,

could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our certificate of incorporation and our bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Stockholder Meetings

Our bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our certificate of incorporation and bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see “Management—Board Composition and Election of Directors.” This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in

any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our convertible preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. This choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction, or the Securities Act. Our certificate of incorporation 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. Additionally, our certificate of incorporation provides that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue convertible preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

Exchange Listing

Our common stock is listed on the Nasdaq Global Market under the symbol "SNSE".

SENSEI BIOTHERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Sensei Biotherapeutics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service upon and following the date of the underwriting agreement between the Company and the underwriters managing the initial public offering of the Company's common stock (the "***Common Stock***"), pursuant to which the Common Stock is priced in such initial public offering (the "***Effective Date***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal quarter, with the pro-rated amount paid on the last day of the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $35,000
   b. Independent Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000

2. Annual Committee Chair Service Retainer:
   a. Chair of the Audit Committee: $15,000
   b. Chair of the Compensation Committee: $10,000
   c. Chair of the Nominating and Corporate Governance Committee: $8,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $5,000
   c. Member of the Nominating and Corporate Governance Committee: $4,000

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2021 Equity Incentive Plan (the "***Plan***"), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise

1.

price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grants: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase 16,667 shares of Common Stock (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service through each such vesting date and will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date.

2. Annual Grants: On the date of each annual stockholder meeting of the Company held after the Effective Date, each Eligible Director who has served as a non-employee member of the Board for at least six months prior to such stockholder meeting and who continues to serve as a non-employee member of the Board following such stockholder meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase 8,333 shares of Common Stock (the "***Annual Grant***"). The shares subject to the Annual Grant will vest in equal monthly installments over a one year period such that the option is fully vested on the first anniversary of the date of grant, subject to the Eligible Director's Continuous Service through each such vesting date; provided, that the Annual Grant will in any case be fully vested on the date of Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service through such vesting date; provided, further, that the Annual Grant will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date.

Non-Employee Director Compensation Limit

Notwithstanding the foregoing, the aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director (as defined in the Plan) shall in no event exceed the limits set forth in Section 3(d) of the Plan.

Exhibit 23.1

Consent of Independent Registered Accounting Firm

We consent to the incorporation by reference in Registration Statement No. 333-252954 on Form S-8 of our report dated March 30, 2021, relating to the financial statements of Sensei Biotherapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Baltimore, Maryland
March 30, 2021

Exhibit 31.1

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

I, John Celebi, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Sensei Biotherapeutics, 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)) for the registrant and have:

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

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

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 30, 2021

By: /s/ John Celebi
John Celebi
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Erin Colgan, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2020 of Sensei Biotherapeutics, 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)) for the registrant and have:

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

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

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 30, 2021

By: /s/ Erin Colgan
Erin Colgan
Senior Vice President of Finance and Administration
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John Celebi, President and Chief Executive Officer of Sensei Biotherapeutics, Inc. (the "Company"), and Erin Colgan, Senior Vice President of Finance and Administration of the Company, each hereby certifies that, to the best of his or her knowledge:

(1) The Company's Annual Report on Form 10-K for the year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 30th day of March, 2021.

/s/ John Celebi
John Celebi
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Erin Colgan
Erin Colgan
Senior Vice President of Finance and Administration
(Principal Financial Officer)

* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.