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 001-36548

ATARA BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-0920988**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Blvd., Suite 900 **South San Francisco, CA**	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: **(650) 278-8930**

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share ,	ATRA	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, a smaller reporting company, or an emerging growth company. See 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	☐	Small reporting company	☐
Emerging growth company	☐		

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

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

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

The aggregate market value of common stock held by non-affiliates of the Registrant, based on the closing sales price for such stock on June 30, 2020 as reported by The Nasdaq Stock Market, was $906,895,284. This calculation excludes 12,063,880 shares held by executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the Registrant.

The number of outstanding shares of the Registrant's Common Stock as of February 18, 2021 was 83,614,853.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

ATARA BIOTHERAPEUTICS, INC.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements, which represent our intent, belief or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "predict," "plan," "expect" or the negative or plural of these words or similar expressions. The forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the timing of initiating clinical studies, opening client sites, enrolling clinical studies and reporting results of clinical studies for our programs, including in light of the COVID-19 pandemic;
- the likelihood and timing of regulatory submissions or related approvals for our product candidates, including the initiation, completion and expectations about the timing of approvals for our BLA for tab-cel® for patients with EBV+ PTLD;
- the potential indications for our product candidates, if approved for commercial use;
- the potential market opportunities for commercializing our product candidates;
- our Research, Development and License Agreement with Bayer, including potential milestone and royalty payments under the agreement;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- estimates of our expenses, capital requirements and need for additional financing;
- our expectation regarding the length of time that our existing capital resources will be sufficient to enable us to fund our planned operations;
- our ability to commercialize our product candidates, if approved for commercial use;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical studies;
- the initiation, timing, progress and results of future preclinical studies and clinical studies and our research and development programs;
- the scope of protection we are able to obtain and maintain for the intellectual property rights covering our product candidates;
- our financial performance;
- developments and projections relating to our competitors and our industry;
- our ability to manufacture our product candidates for our clinical studies, or if approved, for commercial sale;
- the impact of COVID-19 to our business and operations, as well as the businesses and operations of third parties on which we rely;
- our ability to sell or manufacture approved products at commercially reasonable values; and
- timing and costs related to qualification of our manufacturing plant for commercial production.

These statements are only current predictions and are subject to known and unknown risks, uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; the COVID-19 pandemic, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in South San Francisco and Southern California and at our clinical trial sites, as well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of our cash resources and need for additional capital, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this report in greater detail under the heading "1A. Risk Factors" and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

In this Annual Report on Form 10-K, unless the context requires otherwise, "Atara," "Atara Biotherapeutics," "Company," "we," "our," and "us" means Atara Biotherapeutics, Inc. and, where appropriate, its subsidiaries.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. These risks are more fully described below. These risks include, among others:

- we have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future;
- we currently have no approved products and thus have no revenues from commercialization of any products and may never generate product revenues or achieve profitability;
- we are early in our development efforts, and we will need to successfully complete preclinical and clinical testing of our product candidates before we can seek regulatory approval and potentially generate commercial sales;
- we will require substantial additional financing to achieve our goals, which may not be available to us on acceptable terms, or at all;
- our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel;
- the results of preclinical studies or earlier clinical studies are not necessarily predictive of future results, and product candidates we advance into clinical studies may not have favorable results in later clinical studies or receive regulatory approval;
- clinical drug development, both in the U.S. and international jurisdictions, involves a lengthy and expensive process with an uncertain outcome and even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties;
- our T-cell immunotherapy product candidates and our next-generation CAR T programs represent new therapeutic approaches that could result in heightened regulatory scrutiny and delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates;
- the market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small;
- we may not be able to obtain or maintain orphan drug exclusivity for our product candidates;
- the COVID-19 pandemic continues to impact our business and operations and could materially and adversely affect our business and operations in the future, as well as the businesses and operations of third parties on which we rely;
- our success depends upon our ability to obtain and maintain sufficient intellectual property protection for our product candidates, and we may not be able to protect our intellectual property rights throughout the world;
- our principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval; and
- we may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture some or all of our product candidates.

PART I

Item 1. Business

Overview

Atara Biotherapeutics is a pioneer in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with serious diseases, including solid tumors, hematologiccancers and autoimmune disease. With our lead program in Phase 3 clinical development, we are the most advanced allogeneic T-cell immunotherapy company and intend to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-driven diseases or other serious diseases through incorporation of engineered chimeric antigen receptors (CARs) or T-cell receptors (TCRs). Atara is applying this one platform to create a robust pipeline. Our strategic priorities are:

- ***Tab-cel®***: Atara's most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), currently in Phase 3 development for patients with EBV-driven post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-driven diseases;
- ***ATA188***: T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis;
- ***CAR T Programs***:
    - ***ATA2271***: Autologous CAR T immunotherapy targeting solid tumors expressing the tumor antigen mesothelin, which is partnered with Bayer AG (Bayer);
    - ***ATA3271***: Allogeneic CAR T therapy targeting mesothelin, which is partnered with Bayer; and
    - ***ATA3219***: Allogeneic CAR T targeting CD19 and being developed as a potential best-in-class product, based on a next generation 1XX co-stimulatory domain and the innate advantages of EBV T cells as the foundation for an allogeneic CAR T platform.

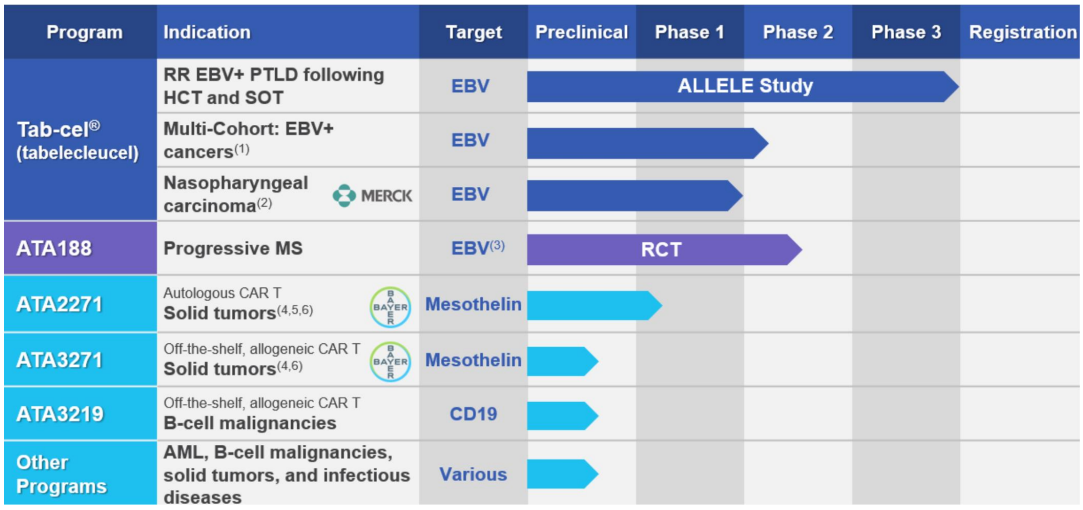
Our T-cell immunotherapy platform includes the capability to progress both allogeneic and autologous programs and is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. For our allogeneic programs, we select the appropriate set of cells for use based on a patient's unique immune profile. In addition, our manufacturing facility has the flexibility to manufacture multiple T-cell and CAR T immunotherapies while integrating research and process science functions to enable increased collaboration for rapid product development. We are currently in the process of completing our facility's commercial production qualification activities for tab-cel® while building inventory according to our commercial product supply strategy.

In December 2020, we entered into a Research, Development and License Agreement with Bayer (the Bayer License Agreement) pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271. See section 'Terms of Certain License and Research and Development Collaboration Agreements' below for additional details.

We have also entered into research collaborations with leading academic institutions such as Memorial Sloan Kettering Cancer Center (MSK), the Council of the Queensland Institute of Medical Research (QIMR Berghofer) and H. Lee Moffitt Cancer Center and Research Institute (Moffitt) pursuant to which we acquired rights to novel and proprietary technologies and programs.

Pipeline

Our pipeline is summarized below:



These investigational agents are not approved by any regulatory agencies. Efficacy and safety have not been established.

EBV+ PTLD: EBV-driven Post-Transplant Lymphoproliferative Disease; RR: rituximab relapsed/refractory; HCT: allogeneic hematopoietic cell transplant; SOT: solid organ transplant

Other programs: ATA2321 (AML), ATA2431 (B-cell malignancies), and ATA368 (HPV)

(1) Phase 2 multi-cohort initiated in Q3 2020, with possible indications including EBV+ PTLD with CNS involvement, EBV+ PID/AID LPD, EBV+ LMS and other potential EBV-driven diseases

(2) Phase 1b/2 study in combination with anti-PD-1 therapy, KEYTRUDA ® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-driven NPC

(3) Targeted antigen recognition technology; Phase 2 Randomized Controlled Trial

(4) Mesothelin is expressed at high levels on the surface of cells in aggressive solid tumors including mesothelioma, triple-negative breast cancer, esophageal cancer, pancreatic cancer and non-small cell lung cancer

(5) Atara's CAR T collaboration with MSK will focus on development of a next-generation, mesothelin-targeted CAR T using novel 1XX CAR signaling and PD-1 dominant negative receptor (DNR) checkpoint inhibition technologies

(6) Worldwide license agreement and research, development and manufacturing collaboration with Bayer to develop Atara's allogeneic off-the-shelf mesothelin CAR T program (ATA3271) and autologous program (ATA2271)

Tab-cel®

EBV+ PTLD

Since its discovery as the first human oncovirus, EBV has been implicated in the development of a wide range of diseases, including lymphomas and other cancers. EBV is widespread in human populations and persists as a lifelong, asymptomatic infection. In healthy individuals, a small percentage of T cells are devoted to keeping EBV in check. In contrast, immunocompromised patients, such as those undergoing hematopoietic cell transplants (HCT) or solid organ transplants (SOT) have a reduced ability to control EBV. Left without appropriate immune surveillance, EBV-transformed cells can, in some patients, proliferate and cause an aggressive, life-threatening cancer called EBV+ PTLD. Nearly all cases of PTLD that occur following HCT are EBV positive while approximately 60% of PTLD cases that occur following SOT are EBV positive.

Historical studies suggest a high unmet medical need for improved therapies in patients with EBV+ PTLDwho have failed rituximab or rituximab plus chemotherapy, with approximately 40% to 60% of patients either not responding to or progressing following this first line of therapy. Expected median overall survival in patients with EBV+ PTLD following HCT who have failed rituximab-based first line therapy is approximately 1.7 months, and for patients with EBV+ PTLD following SOT who have failed rituximab-based first line therapy, the median overall survival is approximately 3.3 months. The use of chemotherapy in patients with EBV+ PTLDwho have failed rituximab is frequently associated with significant rates of treatment-related mortality due to the frailty of the patients and severe toxicities associated with chemotherapy. Based on our market research, we estimate there were several hundred EBV+ PTLD patients who failed rituximab or rituximab plus chemotherapy in the U.S. in 2019.

Tab-cel® for EBV+ PTLD

In June 2015, we licensed certain patent rights, know-how and a library of T cells and cell lines specific to EBV fromMSK under an exclusive license agreement. In accordance with the license agreement, we agreed to use commercially reasonable efforts to commercialize the licensed products and to make milestone payments with respect to the licensed programs and to make royalty payments to MSK to the extent product candidates arising from the collaboration are commercialized. Our most advanced product candidate, tab-cel®, is part of this MSK collaboration and targets EBV.

Tab-cel® is an allogeneic EBV-specific T-cell immunotherapy that is currentlyin Phase 3 development for the treatment of patients withEBV+ PTLD who have failed rituximab or rituximab plus chemotherapy. Tab-cel® is also under development for other EBV+ diseases with significant unmet medical need through a Phase 2 multi-cohort study that was initiated in the third quarter of 2020.

Tab-cel® has received Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration (FDA)for the treatment of patients withEBV+ PTLD after HCT who have failed rituximab, PRIority MEdicines (PRIME) designation from theEuropean Medicines Agency (EMA) for the same indication, and orphan designation in the U.S. and European Union (EU) for the treatment of patients with EBV+ PTLD following HCT or SOT.

In clinical studies conducted at MSK that have enrolled patients withEBV+ PTLD following HCT and SOT, efficacy following treatment with tab-cel® monotherapy compared favorably with historical data in these patient populations. Patients with EBV+ PTLD after HCT who have failed rituximab and were treated with tab-cel® had two-year overall survival of approximately 83% in two separate clinical studies. In the setting of EBV+ PTLD after SOT in patients who have failed rituximab, similar results were observed, with two-year overall survival of approximately 86% in tab-cel®-treated patients. A response rate of greater than or equal to 50% was observed in HCT and SOT patients in these studies.

In December 2017, we initiated two Phase 3studies for tab-cel® intended to support approval in two separate indications, the treatment ofEBV+ PTLD following HCT (which was referred to as the MATCH study) and SOT in patients who have failed rituximab (which was referred to as the ALLELE study). In 2019, after discussion and alignment with regulators, we combined MATCH and ALLELE into a single study (which we now refer to as the ALLELE study) that now consists of an HCT cohort for EBV+ PTLD patients who have failed rituximab, and a single SOT cohort for EBV+ PTLD patients who have failed prior treatment with rituximab with or without chemotherapy. Additionally, we expanded the ALLELE study geographically to include clinical sites in Europe and Canada.

We completed an interim analysis for the ALLELE study in the third quarter of 2020. Data from the interim analysis showed a 50 percent objective response rate (ORR) to tab-cel® with independent oncologic and radiographic assessment (IORA) in patients with relapsed-refractory EBV+ PTLD following HCT or SOT, that had reached at least six months follow-up after the ORR assessment. This ORR is consistent with previously published investigator assessed data. The tab-cel® safety profile is also consistent with previously published data, with no new safety signals.

In January 2021, we presented transcriptional data for tab-cel® at the 2021 Transplantation & Cellular Therapy Meeting demonstrating consistency of the product's activation profile irrespective of donor and consistent enrichment of receptors targeting EBV-driven diseases.

Prior to initiating the BLA, we require a procedural decision from the FDA related to how the historical non-pivotal data should be presented in the BLA submission. Following FDA agreement in October 2020 that the pivotal ALLELE data will be the primary basis for approval, and that historical non-pivotal clinical data will be supportive, the FDA needs to decide whether they view the drug product manufactured by our academic partner used in historical, non-pivotal studies as comparable to the drug product manufactured by Atara used in the pivotal ALLELE study. This decision will then determine if we will submit in the clinical module the pivotal and non-pivotal data combined in pooled analyses or separately in parallel analyses. The type of analysis does not change expectations regarding the proposed product indication for previously treated patients with EBV+ PTLD.

We continue to have ongoing active and productive dialogue with the FDA, which has already resulted in several key points of agreement, including: (i) a rolling submission is acceptable for the BLA, (ii) we can complete the BLA submission with currently enrolled patients in the pivotal ALLELE study with at least six-months follow-up of duration of response, and (iii) the FDA will consider historical data from the Phase 2 trials conducted at MSK, our Phase 2 multicenter expanded access protocol (EAP) and the Single Patient Use (SPU) program as supportive data to the pivotal ALLELE study in the BLA clinical module. We have completed the preclinical module 4 and are ready to initiate a rolling BLA with this module once the FDA decides on a procedural question related to how the historical non-pivotal data should be presented in the BLA submission. We are also making progress through active and productive discussions with the FDA to align on the final content of the chemistry, manufacturing and control (CMC) module 3 of the BLA.

We remain on track to complete a rolling BLA submission for patients with EBV+ PTLD with the clinical module in the third quarter of 2021. We expect to present data from the pivotal ALLELE study at an appropriate congress in the fourth quarter of 2021. We anticipate potential approval of the BLA in the first half of 2022.

We are also planning to submit a tab-cel® marketing authorization application (MAA) for patients with EBV+ PTLD in the EU in the fourth quarter of 2021. We received a positive opinion from the Pediatric Committee (PDCO) of the EMA regarding a Pediatric Investigation Plan (PIP) in November 2020, and the EMA ratified our PIP in December 2020. We anticipate potential approval of the MAA in the second half of 2022.

While clinical study operations and the opening of additional ALLELE sites in the United States, Canada and Europe have been impacted by the spread of COVID-19, most sites are currently open for patient enrollment.

We are continuing our preparations and investing further in commercial readiness activities in anticipation of planned commercialization of tab-cel® in the U.S. We expect to pursue approvals in key geographies and are seeking a partner for the commercialization of tab-cel® outside the U.S.

Tab-cel® Multi-Cohort Study

We continue to pursue development of tab-cel® in earlier lines of therapy with the goal of expanding the potential label in PTLD and closely related diseases. We intend to focus on extending further into immunodeficiency-associated lymphoproliferative diseases (IA-LPDs) as the next step in the tab-cel® potential label expansion given the commonality of their EBV-driven mechanism of disease in immunocompromised patients, high unmet medical need and positive clinical data to date with tab-cel®. We initiated a Phase 2 multi-cohort study in the third quarter of 2020 concurrently in the U.S. and EU. The multi-cohort study will evaluate both treatment-naïve and previously treated patients in six patient populations, including four within IA-LPDs and two in other EBV-driven diseases. Data from this Phase 2 study is expected in 2023.

Data was featured in an e-poster at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress in September 2020 and demonstrated that tab-cel® was well-tolerated and showed encouraging clinical activity in patients with EBV+ AID-LPD and EBV+ PID-LPD (Acquired and Primary Immunodeficiency Lymphoproliferative Diseases).

In patients where previous treatments have failed, the objective response rates, including complete response, were 33.3% (three out of nine patients) in AID-LPD and 37.5% (three out of eight patients) in PID-LPD groups. Tab-cel® was generally well-tolerated with a favorable safety profile consistent with previously published clinical studies. Data on tab-cel® in patients with life-threatening complications stemming from persistent EBV viremia were presented at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition in December 2020. These clinical data demonstrated that tab-cel® was well-tolerated and showed encouraging clinical activity in this patient population, with objective response rates ranging from 50% (two out of four patients) to 80% (four out of five patients). The overall survival (OS) rate at one year in patients with EBV viremia treated in the EAP-201 study was 100 percent for a median follow-up of 14.6 months (min 12.2, max 17.8).

Tab-cel® for NPC

Nasopharyngeal carcinoma (NPC) is a type of head and neck cancer that is primarily associated with EBV. Standard treatment for NPC typically includes radiation therapy, platinum-based chemotherapy or a combination of both. Surgical intervention is only rarely employed and is usually only utilized in select early-stage cases. There are no approved therapeutic agents available to treat relapsed/refractory NPC, although there are multiple agents in development for this patient population.

In April 2017, we entered into an agreement with Merck Sharp & Dohme (known as MSD outside of the U.S. and Canada) to provide drug supply for a study to be sponsored and conducted by us to evaluate tab-cel® in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-driven NPC. Our Phase 1b study, which was initiated in 2018, achieved its safety endpoints and stable disease in some patients. Based on a strategic prioritization to expand tab-cel® business potential through the significant opportunity in IA-LPDs, we will focus our tab-cel® efforts on the execution of the Phase 2 multi-cohort study and the planned BLA initiation in EBV+ PTLD. At this time, we will not initiate the Phase 2 portion of the NPC study in combination with pembrolizumab. We intend to generate additional translational data in NPC in 2021 to further inform our strategy on this patient population. We plan to share data from the NPC study at an appropriate forum in the future.

ATA188

Multiple Sclerosis

We are also developing ATA188, an allogeneic T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). MS is a chronic autoimmune disorder of the central nervous system (CNS) that disrupts the myelination and normal functioning of the brain, optic nerves and spinal cord through inflammation and tissue loss. The evolution of MS results in an increasing loss of both physical and cognitive (e.g., memory) function. This has a substantial negative impact on the approximately 2.3 million patients worldwide diagnosed and living with MS, with approximately one million of those patients having a progressive form of MS.

There are two categories of MS: progressive MS (PMS) and relapsing-remitting MS (RRMS). RRMS is a form of MS that is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery and quiescence during which the disease does not progress. PMS is a severe form of MS that is characterized by persistent progression and worsening of MS symptoms and physical disability over time for which there are few therapeutic options. There are two types of PMS: primary progressive MS (PPMS) and secondary progressive MS (SPMS). PPMS occurs when the patient has a disease course characterized by steady and progressive worsening after disease onset. SPMS initially begins as RRMS, but once patients have continuous progression of their disease, they have developed SPMS.

Scientific and clinical findings support a potential biologic connection between EBV and MS. EBV is present in nearly all patients with MS. The MS disease course has been shown to correlate with measures of EBV activity, and with exhaustion of endogenous EBV-specific T cell populations. In addition, in separate studies, clear differences in location and frequency of EBV-infected B cells and plasma cells were evident between the brains of subjects without MS and the brains of MS patients, where EBV-infected B cells and plasma cells were in close proximity to areas of active demyelination. Further data suggest that EBV-positive B cells and plasma cells in the CNS have the potential to catalyze an autoimmune response, resulting in the typical MS pathophysiology. In patients with MS, their T cells may be unable to control EBV-positive B cells and plasma cells so that B cells and plasma cells could then accumulate in the brain, function as antigen-presenting cells and generate antibodies that attack and destroy myelin, the protective layer that insulates nerves in the brain and spinal cord. This loss of myelin ultimately leads to MS symptoms. The role of B cells in MS is supported by the approval by the FDA of ocrelizumab for PPMS, which broadly targets B cells (and not plasma cells) outside of the CNS through their expression of a cell surface marker known as CD20.

Based on our analysis of industry data and assumed increases in treatment rates and market share for a best-in-class treatment, we estimate that the potential annual U.S. market opportunity in PMS could be at least $3.5 billion by 2025.

ATA188 for MS

We licensed rights to certain know-how and technology from QIMR Berghofer that uses targetedantigen recognition to create off-the-shelf T-cell immunotherapy product candidates applicable to a variety of diseases, including autoimmune conditions such as MS. Our license agreement with QIMR Berghofer requires that we make various milestone and royalty payments to QIMR Berghofer based on the sales of products arising from this collaboration, if any. We are also working with QIMR Berghofer on the development of EBV-targeted and other virally targeted T cells. Through this technology, we are expanding the role of T-cell-based immunotherapy beyond oncology and viral infections to autoimmune diseases.

Our T-cell immunotherapy product candidate utilizing this technology, ATA188, is an off-the-shelf EBV-specific T-cell preparation that utilizes an MS-specific targeted antigen recognition technology that enables the T cells we administer to selectively identify cells expressing the EBV antigens that we believe are important for the potential treatment of MS. ATA188 is designed to selectively target only those cells which are EBV-positive while sparing those that are not. We believe that eliminating only EBV-positive B cells and plasma cells has the potential to benefit some patients with MS.

In the fourth quarter of 2017, we initiated an open label, single arm, multi-center, multi-national Phase 1 study with allogeneic ATA188 for patients with PMS. The primary objective of this Phase 1 study is to assess the safety of ATA188 in patients followed for at least one year after the first dose. Key secondary endpoints in the study include measures of clinical improvement, using recognized scales for MS symptoms, function and disability including Expanded Disability Status Scale(EDSS), Fatigue Severity Score, MS Impact Scale-29 (physical), Timed 25-Foot Walk (T25FW), 9-Hole Peg Test, 12-Item MS Walking Scale (MSWS-12) and Visual Acuity.

Enrollment for the fourth and final dose escalation cohort in the Phase 1a portion of the study was completed in the third quarter of 2019 and we presented updated efficacy and safety results from this study at the MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting in September 2020. The data demonstrated that ATA188 was well-tolerated across all four dose cohorts, with no dose-limiting toxicities and no fatal adverse events. Additionally, patients who demonstrated sustained disability improvement (SDI) at any timepoint maintained improvement at all future timepoints, and higher proportion of patients showed SDI with increasing dose (42% in cohorts 3 and 4 (higher doses) versus 17% in cohorts 1 and 2 (lower doses)). SDI is defined as clinically significant improvement in EDSS or T25FW observed at two consecutive time points. ATA188 treatment showed no clinically meaningful effect on cytokine levels and no dose-related safety trends were identified. Rhinorrhea (runny nose) was the only treatment-related event that occurred in more than one subject. No dose-limiting toxicities and no fatal adverse events have been reported. The safety profile has remained consistent with previously reported data. We also presented preclinical translation data at ACTRIMS-ECTRIMS that further support the proposed mechanism of action of ATA188 targeting EBV-infected B cells. These combined analyses of T cells comprising ATA188 are consistent with its proposed mechanism of targeting EBV-infected B cells by recognizing MS-relevant EBV antigens on these cells via defined TCRs. While these data will need to be confirmed in a double-blind, placebo-controlled, randomized study, they indicate the potential for the first treatment option in PMS to halt or reverse the progression of disease. We believe these results align with the body of evidence supporting the important role of EBV-infected B cells in the chronic autoimmune pathology of MS.

We are also re-treating patients with Cohort 3 dose in an open-label extension (OLE) of the Phase 1a study and we presented the first available data from the OLE at the ACTRIMS-ECTRIMS Meeting in September 2020. We presented updated data from the OLE in an e-poster at the European Charcot Foundation 28th Annual Meeting in November 2020, including data on 24 patients from the 12-month dose escalation portion of the trial, 16 of whom entered the OLE and had ≥15-month data available as of October 2020. Throughout the entire Phase 1a and OLE study, nine of the 16 patients who entered the OLE demonstrated SDI with ATA188 treatment (seven achieved SDI in the first 12 months and two during the OLE). In seven out of the nine patients, SDI was driven by sustained improvement in EDSS. A dose-related increase in the number of patients meeting SDI criteria was observed. Similar safety profile with no dose-limiting toxicities was shown in the highest dose cohorts (Cohorts 3 and 4). In the two highest dose cohorts, five out of 12 total patients (42%) and six out of 12 total patients (50%) demonstrated SDI at 12 and 15 months, respectively. SDI was driven by EDSS in all but one of the patients in Cohorts 3 and 4; all SDI observed in Cohort 4 was based on EDSS improvement. The Cohort 3 and 4 doses demonstrated similar efficacy profile based on SDI, with the Cohort 4 dose trending toward greater effect on EDSS. We plan to re-treat patients in the OLE with Cohort 4 dose in subsequent years. We plan to present translational data in the first half of 2021 at an appropriate forum and long-term two-year clinical data from the OLE in the second half of 2021.

In January 2021, we presented a poster at the 2021 Transplantation & Cellular Therapy Meeting an innovative testing solution that enables detection and quantification of non-engineered allogeneic T-cell therapies for use in ATA188 clinical development.

We initiated a randomized, double-blind, placebo-controlled trial (RCT) to evaluate the efficacy and safety of ATA188 in patients with PMS using the cohort 3 dose and enrolled the first patient in June 2020. This study was previously designated as Phase 1b and, based on recent program changes, it is now designated as a Phase 2. We discussed updates to the design of the RCT study with the FDA in January 2021 and gained alignment on several points for the RCT, as well as potential registrational studies: (i) a disability improvement endpoint is appropriate, with the FDA articulating a preference for EDSS improvement; (ii) the criteria used to enroll the study population of SPMS and PPMS are appropriate; and (iii) the Phase 2 RCT should run for at least 12 months, and a properly conducted interim analysis is appropriate. We also submitted a protocol amendment to the FDA, increasing the number of patients to 80, changing the primary end point of the study to EDSS disability improvement and maintaining the biological and functional endpoints. We plan to continue discussions with the FDA about potential opportunities for accelerated development of ATA188. We plan to conduct an interim analysis to assess efficacy and safety in the first half of 2022 and following the interim analysis, we expect to complete planned enrollment of the Phase 2 RCT in the first half of 2022. Based on the most recent data from the Phase 1a portion of the study, which shows a higher proportion of patients showing sustained EDSS improvements and a consistent safety profile over 15 months, we have selected the cohort 4 dose for enrollment in the Phase 2 RCT. In addition to measuring change in disability measures compared to baseline, especially SDI over time, the study also includes multiple measures of patients' function as well as various biomarkers.

CAR T Programs

Our current CAR T pipeline is as follows:

	Indication	Target	CAR T Technologies	
ATA2271 [1]	Autologous **Solid tumors**[2]	Mesothelin	PD-1 DNR 1XX co-stimulation	Memorial Sloan Kettering Cancer Center
ATA3271 [1]	Off-the-shelf, allogeneic **Solid tumors**[2]	Mesothelin	PD-1 DNR 1XX co-stimulation	ATARA BIO
ATA3219	Off-the-shelf, allogeneic **B-cell malignancies**	CD19	1XX co-stimulation	ATARA BIO
ATA2321	Autologous **AML**	Dual-targeted undisclosed	Mut06 co-stimulation	MOFFITT CANCER CENTER
ATA2431	Autologous **B-cell malignancies**	CD19-CD20	Mut06 co-stimulation	MOFFITT CANCER CENTER
Other CAR T	**Infectious diseases**	Undisclosed	1XX co-stimulation	Memorial Sloan Kettering Cancer Center

AML: acute myeloid leukemia; DNR: Dominant Negative Receptor

(1) Worldwide license agreement and research, development and manufacturing collaboration with Bayer to develop Atara's allogeneic off-the-shelf mesothelin CAR T program (ATA3271) and autologous program (ATA2271)

(2) Mesothelin is expressed at high levels on the surface of cells in aggressive solid tumors including mesothelioma, triple-negative breast cancer, esophageal cancer, pancreatic cancer and non-small cell lung cancer

ATA2271/ATA3271

Our next-generation CAR T immunotherapy programs include autologous ATA2271 and allogeneic ATA3271 targeting mesothelin, which is a tumor antigen expressed on a number of solid tumors including mesothelioma, ovarian cancer, pancreatic cancer, non-small cell lung cancer and other tumors over-expressing mesothelin. ATA2271 is designed to improve efficacy persistence, and durability of response versus CD28/CD3z-based CARs by using a novel 1XX CAR co-stimulatory signaling domain and cell intrinsic checkpoint inhibition technology with a PD-1 dominant negative receptor (DNR).

In 2018, we entered into several agreements to expand our collaboration with MSK to the development of CAR T immunotherapies, with a license in May 2018 related to multiple collaboration targets and a license in December 2018 related to our next-generation CAR T program targeting mesothelin. Under these CAR T agreements, we agreed to use commercially reasonable efforts to develop, obtain regulatory approval and, if approved, commercialize certain collaboration targets and to make certain milestone and royalty payments.

Data from investigational new drug (IND) enabling studies for ATA2271 were presented at the American Association for Cancer Research (AACR) Virtual Meeting II in June 2020. These data support the first application of the combination of 1XX co-stimulatory domain and cell intrinsic checkpoint inhibition technology with a PD-1 DNR that are associated with less cell exhaustion, improvements in functional persistence, serial cell killing and in vivo efficacy, which was maintained through multiple tumor re-challenges when compared with first-generation CD28/CD3z-based mesothelin CAR. The FDA accepted the IND application submitted by our collaborators at MSK in August 2020, and in September 2020, MSK initiated an open-label, single-arm Phase 1 clinical study of ATA2271 for patients with advanced mesothelioma. MSK has enrolled several patients into this study and we expect first Phase 1 data from this study to be presented in the fourth quarter of 2021.

We are also developing and have initiated IND-enabling studies for ATA3271, an off-the-shelf, allogeneic CAR T therapy targeting mesothelin using a PD-1 DNR and 1XX CAR co-stimulatory signaling domain through our EBV T-cell platform, and we expect to file the IND in the second half of 2022. Preclinical data for ATA3271 demonstrates potent anti-tumor activity, functional persistence and significant survival benefit with no evidence of allocytotoxicity in vivo, suggesting that allogeneic MSLN-CAR-engineered EBV T cells are a promising approach for the treatment of MSLN-positive cancers. These data were presented at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting in November 2020.

In December 2020, we entered intothe Bayer License Agreement pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271. See section 'Terms of Certain License and Research and Development Collaboration Agreements' below for additional details.

ATA3219

We are also developing ATA3219, an off-the-shelf, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies as a potential best-in-class therapy without the need for TCR gene editing, using our next-generation 1XX CAR co-stimulatory domain and EBV T-cell platform.

In February 2020, an academic off-the-shelf, allogeneic CD19 CAR T clinical study using an allogeneic EBV T-cell construct and CD28/CD3z co-stimulatory domain for patients with relapsed/refractory B-cell malignancies was presented at the 2020 Transplantation and Cellular Therapy (TCT) Meetings. Findings from this study provided initial clinical proof-of-principle that an EBV T-cell platform has the potential to generate off-the-shelf, allogeneic CAR T immunotherapies with high response rates, durable responses and low risk of toxicity that can be rapidly delivered to patients.

Preclinical data for ATA3219 demonstrate functional persistence, polyfunctional phenotype and efficient targeting of CD19-expressing tumor cells both in vitro and in vivo. An abstract detailing this ATA3219 preclinical data was presented at the 62nd ASH Annual Meeting and Exposition in December2020.

We had a pre-IND meeting with the FDA in October 2020, where we received feedback to guide the IND filing for ATA3219. We have initiated IND-enabling studies and plan to submit an IND for ATA3219 for patients with B-cell malignancies in the fourth quarter of 2021 or first quarter of 2022.

Additional Programs and Platform Expansion Activities

In addition to the prioritized programs described above, we have a number of preclinical programs. For example, in August 2018, we entered into a strategic collaboration with Moffitt. As part of this relationship, we agreed to collaborate with Moffitt to develop multi-targeted CAR T immunotherapies designed to address cancers with diverse cell types that often become resistant to treatment, such as acute myeloid leukemia (AML) (ATA2321) and B-cell malignancies (ATA2431), and to make certain milestone and royalty payments associated with the collaboration targets. In addition, the collaboration includes the use of a novel CAR T intracellular co-stimulatory domain that may improve CAR T proliferation when responding to an appropriate antigen and enhance CAR T persistence by reducing T-cell exhaustion. In addition to our ATA188 program with QIMR, we are also collaborating with QIMR on the development of ATA368 for patients with human papillomavirus (HPV) associated cancers.

We believe our platform will have utility beyond the current set of targets to which it has been directed.We continue to evaluate additional product candidates, including those derived from collaborations with our partners. We expect to further research and develop additional cellular therapies, which may include T-cell programs targeted against other antigens as well as engineered T-cell immunotherapies such as CAR T-cell programs. We believe that viral antigens are well suited to adoptive immunotherapy given that people with normal immune systems are able to mount robust responses to these viral targets, but immunocompromised patients and some cancer patients are not. We also continue to evaluate opportunities to license or acquire additional product candidates or technologies to enhance our existing platform.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidates. Some of these competitors or potential competitors have significantly greater established presences in the market, financial resources and technical expertise than we do. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop.

Should any of our T-cell product candidates be approved for use, we will face substantial competition. In addition to the current standard of care for patients, commercial and academic clinical studies are being pursued by a number of parties in the field of immunotherapy. Early results from these studies have fueled continued interest in T-cell immunotherapy. In addition, if approved, our T-cell programs would compete with currently marketed drugs and therapies used for treatment of the indications we are addressing, and potentially with product candidates currently in development for the same indications.

EBV+ PTLD

There are currently no FDA- or EMA-approved products for the treatment of EBV+ PTLD. However, some marketed products and therapies are used off-label in the treatment of EBV+ PTLD, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing product candidates for EBV+ PTLD and other EBV-driven diseases including: Viracta Therapeutics, Inc., which is conducting a Phase 1b/2 clinical study for nanatinostat (formerly named tractinostat, or VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas; AlloVir (formerly known as ViraCyte), which has completed a Phase 2 clinical study for Viralym-M (ALVR105), an allogeneic, multi-virus T-cell product that targets six viruses in allogeneic HSCT recipients with ≥1 treatment-refractory infection, including EBV, and is planning to initiate several Phase 3 studies for CMV, AdV and Virus-Associated Hemorrhagic-Cystitis, as well as a Phase 1b/2 proof of concept trial for the prevention of BKV, CMV, AdV, EBV, HHV06 and JCV; and Tessa Therapeutics Pte Ltd., which has a Phase 2 autologous and preclinical allogeneic CD30-CAR-T product candidate being evaluated in CD30+ lymphomas.

Multiple Sclerosis

Competition in the MS market is high with at least 20 therapies, including four generics or bioequivalents, approved in the U.S. and EU for the treatment of various forms of MS, including clinically isolated syndrome, relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS). There are many competitors in the MS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Kesimpta® (anti-CD20 monoclonal antibody), marketed by Novartis, was approved in the U.S. for the treatment of relapsing forms of MS, and a decision for its approval for treatment of the same indication in the EU is expected in the first half of 2021. Johnson & Johnson has completed Phase 3 studies of its sphingosine-1-phosphate receptor 1 (S1P1) modulator, ponesimod, and has sought regulatory approval also for relapsing forms of MS in the U.S. and EU.

There are numerous development candidates in Phase 3 studies for both relapsing and/or progressive forms of MS and additional novel agents could be approved in either or both indications in the future including TG Therapeutics' anti-CD20 monoclonal antibody ublituximab, EMD Serono's Bruton's tyrosine kinase (BTK) inhibitor, evobrutinib, Roche's BTK inhibitor, fenebrutinib, Sanofi's BTK inhibitor, SAR442168 and AB Science's tyrosine kinase inhibitor, masitinib. Medicinova is planning to initiate a Phase 3 study of its PDE inhibitor, ibudilast (MN166) in non-active SPMS.

CAR T Program

There are currently four autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel), Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus™ (brexucabtagene autoleucel) and Bristol-Myers Squibb's Breyanzi® (lisocabtagene maraleucel). Bristol-Myers Squibb has filed a BLA to the U.S. FDA for idecabtagene vicleucel with bluebird bio. There are many CAR-mediated cell therapies in development, and, although the majority are autologous, they include allogeneic and off-the-shelf cell therapies. There are multiple allogeneic CAR platforms being developed with differences in approaches to minimize instances of donor cells recognizing the patient's body as foreign or rejection of the donor cells by the patient's body. These approaches include the use of gene-editing to remove or inhibit the TCR and the use of cell types without a TCR. The majority of clinical stage allogeneic CAR programs utilize alpha beta T cells as the cell type and gene editing of the T-cell receptor and HLA as the preferred technology approach, however, other strategies are also in development. Depending on the diseases that we target in the future, we may face competition from both autologous and allogeneic CAR therapies and other modalities (e.g., small molecules, antibodies) in the indication of interest.

Terms of Certain License and Research and Development Collaboration Agreements

Out-license

Bayer Research, Development and License Agreement

On December 4, 2020, we entered into the Bayer License Agreement, pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271 (the Licensed Products), in each case, targeting mesothelin.

Under the terms of the Bayer License Agreement, we will be responsible at our cost for all mutually agreed preclinical and clinical activities for ATA2271 through the first in human Phase 1 clinical study in collaboration with MSK, following which Bayer will be responsible for the further development of ATA2271 at its cost. Bayer will be responsible for the development of ATA3271, except for certain mutually agreed preclinical, translational, manufacturing and supply chain activities to be performed by us relating to ATA3271, in each case at Bayer's cost. Bayer will also be solely responsible for commercializing the Licensed Products at its cost.

In December 2020, we received an upfront cash payment of $45.0 million from Bayer for the exclusive license grant, net of applicable withholding taxes, which we believe are recoverable, and an additional $15.0 million upfront reimbursement payment for certain research and process development activities to be performed by us. We are also entitled to receive (i) up to an additional $5.0 million for additional, specified translational activities under the Bayer License Agreement and (ii) an aggregate of up to $610.0 million in milestone payments upon achieving certain development, regulatory and commercial milestones relating to the Licensed Products. In addition, we are eligible to receive from Bayer tiered royalties at percentages up to low double digits on worldwide net product sales of the Licensed Products on a country-by-country and product-by-product basis until the later of 12 years after the first commercial sale in such country or the expiration of specified patent rights in such country, subject to certain reductions and aggregate minimum floors. We also granted Bayer a time limited, non-exclusive right to negotiate a license to additional Atara CAR-T product candidates if we decide to pursue an out-license of such CAR-T product candidates. Under the terms of the Bayer License Agreement, we are currently negotiating a separate manufacturing and supply agreement with Bayer for the supply of allogenic mesothelin-directed CAR T-cell therapies for clinical trials.

In-license

MSK License Agreements

In June 2015, we entered into a license agreement with MSK, under which MSK granted us a worldwide, exclusive license to certain patent rights, know-how and a library of T cells and cell lines, to research, develop, manufacture and commercialize three clinical stage T-cell therapies. We are obligated to make milestone payments of up to $33.0 million to MSK based on achievement of specified regulatory and sales-related milestones, as well as mid single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any. In addition, under certain circumstances, we must make certain minimum annual royalty payments to MSK, which are creditable against earned royalties owed for the same annual period. We are also obligated to pay a low double-digit percentage of any consideration we receive for sublicensing the licensed rights. The license agreement expires on a licensed product-by-product and country-by-country basis, on the latest of: (i) expiration of the last licensed patent rights related to a licensed product, (ii) expiration of any market exclusivity period granted by law with respect to a licensed product, and (iii) a specified number of years after the first commercial sale of the licensed product in each country. Upon expiration of the license agreement, Atara will retain non-exclusive rights to the licensed products.

In May and December 2018, we licensed additional technology from MSK. We are obligated to make additional milestone payments based on achievement of specified development, regulatory and sales-related milestones as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any.

QIMR Berghofer License Agreements

In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer. Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive and worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology. We exercised this option in June 2018. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019 to terminate our license to certain rights related to cytomegalovirus (CMV). In addition, we further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2020 to terminate our license to certain rights related to BK polyomavirus and JC polyomavirus. We refer to our August 2020 third amended and restated license agreement with QIMR Berghofer as the QIMR License Agreement and our August 2020 third amended and restated research and development collaboration agreement with QIMR Berghofer as our QIMR Collaboration Agreement.

The QIMR License Agreement provides for various milestone and low to mid single-digit royalty payments to QIMR Berghofer based on future product sales, if any. Under the terms of the QIMR Collaboration Agreement, we are required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. The QIMR Collaboration Agreement also provides for various milestone payments to QIMR Berghofer based on the achievement of certain developmental and regulatory milestones.

We have the right at any time to terminate the QIMR License Agreement, at will, by providing written notice of termination to QIMR Berghofer and paying QIMR Berghofer a break-up fee equal to 50 percent of the amount of the next milestone payment that would be payable to QIMR Berghofer. QIMR Berghofer or we may terminate the QIMR Collaboration Agreement at any time if either party determines that the collaboration is no longer academically, technically, or commercially feasible by giving the other party 30-day written notice. In the event of a material breach of either agreement, QIMR Berghofer or we may terminate the agreement if the breaching party does not cure such breach within a specified period.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and non-U.S. patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Some of patents, trademarks, trade secrets, know-how and other intellectual property rights we rely on are owned by us and others are in-licensed from our partners. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license. Additionally, we expect to benefit from a variety of statutory frameworks in the U.S., Europe and other countries that relate to the regulation of biosimilar molecules and orphan drug status. These statutory frameworks provide certain periods of regulatory exclusivity for qualifying molecules. See "Government Regulation."

Patents

We seek composition-of-matter and/or associated method patents, including method-of-treatment patents, for each of our product candidates in key therapeutic areas. The U.S. patent system permits the filing of provisional and non-provisional patent applications. A provisional patent application is not examined for patentability by the U.S. Patent and Trademark Office (USPTO), and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into an issued patent. Provisional patent applications are often used, among other things, to establish an early effective filing date for a later-filed non-provisional patent application. A non-provisional patent application is examined by the USPTO and can mature into a patent once the USPTO determines that the claimed invention meets the standards of patentability.

Individual patents extend for varying periods of time depending on the date of filing of the patent application, the priority date claimed, and the legal term of patents as determined by the applicable law in the countries in which those patents are obtained. Generally, patents issued from applications filed in the U.S. are effective for 20 years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period; however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. Additionally, patent term adjustments can extend term to account for certain delays by the USPTO during prosecution before that office. The duration of non-U.S. patents varies in accordance with provisions of applicable local law, but typically, the life of a non-U.S. patent is 20 years from the earliest international filing date, not inclusive of any patent term extension that may be available. The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

National and international patent laws concerning protein-based biologics such as our products remain highly unsettled. No consistent policy regarding the patent-eligibility or the breadth of claims allowed in patents in this field has emerged to date among the U.S., Europe or other countries. Changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive intellectual property litigation. Our ability to maintain and solidify our proprietary position for our product candidates and technology will depend on our success in obtaining effective claims for our patents and enforcing those claims once a patent is granted. We do not know whether any of our patent applications will result in the issuance of any patents. Our issued patents may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of any drug we may develop from our product candidates, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

Our global patent estate consists of both solely-owned and in-licensed patents and patent applications, is directed to compositions of matter and/or associated methods, including methods of treatment, and consists of 39 patent families having a total of more than 274 issued patents or patent applications. Our patents and patent applications (if issued) are expected to expire between 2023 and 2041, not inclusive of any patent term extension that may be available in any associated jurisdiction.

Trade Secrets

In addition to patents, 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 invention assignment agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by an employee. These agreements may be breached, and we may not have adequate remedies for any such breach or any unauthorized disclosure of our proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trademarks

We also rely upon trademarks to develop and maintain our competitive position, and we continue to pursue and obtain trademark rights relating to our business. We have a vigorous global program of trademark registration and enforcement to maintain and strengthen the value of our trademarks and prevent the unauthorized use of those trademarks. Our global trademark portfolio consists of six different trademark families comprised of more than 90 registrations and pending applications.

Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our T-cell immunotherapies, if approved, will be products regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with current good manufacturing practice (cGMP) for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. Our product candidates are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the U.S. and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the U.S., the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act (FDCA), the Public Health Service Act (PHSA), and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require 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 after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices (GLPs), and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin
- approval by an independent Institutional Review Board (IRB), or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs), and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (GTPs) for the use of human cellular and tissue products;
- potential FDA inspection of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, i.e., licensure of the product candidate that is the subject of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. 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, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent document that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined

- *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and to investigators for serious and unexpected adverse events, findings from other studies, laboratory animal testing or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over the rate listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. 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 or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. 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 has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended (PDUFA), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. 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.

Within 60 days following submission of the application, the FDA reviews a BLA submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making

decisions. During the biological product approval process, the FDA also determines whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. 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. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. GTPs are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue-based products (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. 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.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product 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 data or full or partial waivers.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic 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 U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product, submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy (RMAT) designation was established by FDA in 2017 to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

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

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although a physician may prescribe a legally available product for an off-label use, if the physician deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding 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 products 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 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. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act (BPCIA), amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, 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 Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration 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. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of 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.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. 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.

Reimbursement

In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which the costs of such products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Third-party payors determine which medications they will cover and establish reimbursement levels. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the U.S. Third-party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products.

These third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, in the U.S. there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. Additionally, in May 2018, the Trump administration laid out a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. Several final rules have been recently promulgated that seek to implement several of the Trump administration's proposals. For example, 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 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. Further, on November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented 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, to encourage importation from other countries and bulk purchasing. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Within the U.S., if we obtain appropriate approval in the future to market any of our product candidates, we may seek approval and coverage for those products under Medicaid, Medicare and the Public Health Service (PHS), pharmaceutical pricing program and also seek to sell the products to federal agencies.

Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, manufacturers are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law and may be subject to an additional discount if certain pricing increases more than inflation.

Medicare is a federal program administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time.

Medicare Part B covers most injectable drugs given in an in-patient setting, and some drugs administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for Part B covered drugs based on a percentage of manufacturer-reported average sales price.

Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for a drug product to be covered and paid for by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended to not exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than inflation.

To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Affordable Care Act), which included changes to the coverage and payment for drug products under government health care programs. Since its enactment, there have been judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, President Trump signed Executive Orders designed to eliminate the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In December 2019, the U.S. Court of Appeals for the 5th Circuit upheld a District Court ruling that the individual mandate was unconstitutional and remanded the case back to the Texas District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the Affordable Care act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the U.S. Supreme Court ruling, other such litigation, and the healthcare form measures of the Biden administration will impact the Affordable Care Act and our business.

U.S. Health Care Laws

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with 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 conduct research and would market, sell and distribute our products. As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute, which governs our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information as well as their covered subcontractors;
- the federal physician sunshine requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- state and foreign laws and regulations that are analogous to the federal laws and regulations described in the preceding subsections of this risk factor, 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; some state laws require drug manufacturers to report information regarding pricing and marketing information related to payments and other transfers of value to physicians and other healthcare providers; some state and local laws require the registration of pharmaceutical sales representatives; and other state laws require the protection of the privacy and security of health information, which may differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, California enacted the California Consumer Privacy Act (CCPA), effective January 1, 2020, and the California Privacy Rights Act of 2020 (CPRA) was recently approved by California voters; and
- similar healthcare laws and regulations in the European Economic Area (EEA) and other jurisdictions, the General Data Protection Regulation (EU) 2016/679 (GDPR), which imposes obligations and restrictions on the collection and use of personal information relating to individuals located in the EEA (including health information).

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement, and the curtailment or restructuring of our operations.

Foreign Regulation

In addition to regulations in the U.S., we are subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical studies or market products in those countries or areas. The approval process and requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Certain countries outside of the U.S. have a process that requires the submission of a CTA, which is much like an IND in the U.S., prior to the commencement of human clinical studies. In the EU, for example, in accordance with the requirements of the EU Clinical Trials Directive, as implemented in national law by Member States, a CTA must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical studies. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed in that country. In all cases, the clinical studies must be conducted in accordance with GCP and other applicable regulatory requirements. In 2014, a new Clinical Trials Regulation 536/2014, replacing the current Directive, was adopted. The new Regulation will become directly applicable in all EU Member States (without national implementation) once the EU Portal and Database are fully functional. It is expected that the Regulation will apply in late 2021. The new Regulation seeks to simplify and streamline the approval of clinical trials in the European Union. For example, the sponsor shall submit a single application for approval of a clinical trial via the EU Portal. As part of the application process, the sponsor shall propose a reporting Member State, who will coordinate the validation and evaluation of the application. The reporting Member State shall consult and coordinate with the other concerned Member States. If an approval is issued, the sponsor can start the clinical trial in all concerned Member States. However, a concerned Member State can in limited circumstances declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that Member State. The Regulation also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

Under EU regulatory systems, a company may submit marketing authorization applications under centralized or decentralized, or mutual-recognition procedures. We expect to utilize the centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the EMA, where it will be evaluated by the Committee for Medicinal Products for Human Use. If this committee delivers a favorable opinion, this typically results in the grant by the European Commission of a single marketing authorization that is valid for all EU member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. Conditional marketing authorization in the European Union is permitted based on incomplete clinical data for a limited number of medicinal products for human use, including products designated as orphan medicinal products under EU law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical study data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

As in the U.S., we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 11 years of exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product. The PRIME initiative was established by the EMA to help promote and foster the development of new medicines in the European Union that demonstrate potential for a major therapeutic advantage in areas of unmet medical need. Benefits from the PRIME designation include early confirmation of potential for accelerated assessment, early dialogue and increased interaction with relevant regulatory committees to discuss development options, scientific advice at key development milestones, and proactive regulatory support from the EMA.

In the EU, companies developing a new medicinal product must agree to a PIP with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a deferral or waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Outside the U.S., there are additional challenges in ensuring adequate coverage and payment for our products. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory approval for a product and may require us to conduct a clinical study that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of this type of clinical study could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. Budgetary pressures in many European Union countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. 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.

Brexit and the Regulatory Framework in the United Kingdom

Following the result of a referendum in 2016, the United Kingdom left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the United Kingdom was subject to a transition period until December 31, 2020 (the Transition Period) during which EU rules continued to apply. A UK-EU Trade and Cooperation Deal (the Deal) that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020 and has been approved by each EU member state and the United Kingdom.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom and the EU. Great Britain (made up of England, Scotland and Wales) is no longer covered by the EEA's procedures for the grant of marketing authorizations (Northern Ireland will be covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures). A separate marketing authorization will be required to market drugs in Great Britain. It is currently unclear whether the Medical Healthcare products Regulatory Agency (MHRA) in the United Kingdom is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, would delay or prevent us from commercializing our product candidates in the United Kingdom or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

While the Deal provides for the tariff-free trade of medicinal products between the United Kingdom and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the United Kingdom diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Orphan designation in Great Britain following Brexit is granted on an essentially identical basis to in the EU, but is based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that are currently designated as orphan conditions in Great Britain will no longer be and that conditions that are not currently designated as orphan conditions in the EU will be designated as such in Great Britain.

Additional Regulation

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by, our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Manufacturing

Our manufacturing facility in Thousand Oaks, California has the flexibility to manufacture multiple T-cell and CAR T immunotherapies while integrating research and process science functions to enable increased collaboration for rapid product development. Our research and development and process and analytical development labs are currently supporting preclinical development activities. Our facility is designed to global regulatory standards, and the required facility commissioning and qualification activities to support clinical manufacturing are complete. We are in the process of completing our facility's commercial production qualification activities for tab-cel® while building inventory according to our commercial product supply strategy.

We continue to scale our EBV T-cell manufacturing platform to improve product yields from a single donor leukapheresis and have generated data confirming the use of stirred-tank perfusion bioreactors to improve yield and cell growth productivity. We believe our scale-up technology can potentially be a key enabler to deliver biologic-like cost of goods manufactured and could be leveraged across our portfolio, including our CAR T programs. There have been transient interruptions in the supply of leukapheresis collections related to the COVID-19 pandemic, which supply raw materials used in our product candidates. If we are unable to obtain such raw materials or other necessary raw materials in a timely manner, our business operations and manufacturing capabilities could be adversely affected.

In addition to our manufacturing facility, we also work with Cognate BioServices, Inc. (Cognate) pursuant to a Commercial Manufacturing Services Agreement (the Manufacturing Agreement) that we entered into in December 2019. Pursuant to the Manufacturing Agreement, Cognate provides manufacturing services for certain of our product candidates. The initial term of the Manufacturing Agreement runs until December 31, 2021 and is renewable with Cognate's approval for an additional one-year period. We may terminate the Manufacturing Agreement for convenience on six months' written notice to Cognate, or immediately if Cognate is unable to perform the services under the Manufacturing Agreement or fails to obtain or maintain certain necessary approvals.

Our current manufacturing strategy is to evaluate each product candidate and determine which site in our manufacturing network provides the phase-appropriate technical, quality and regulatory compliance requirements. In addition, the long-range supply requirements of our product candidates are evaluated periodically to ensure we are planning manufacturing capacity and capabilities accordingly across our network. Our manufacturing network is comprised of our own facility and the manufacturing capabilities of our partners, including MSK and an affiliate of QIMR Berghofer, and contract manufacturing organizations (CMOs), including Cognate. This strategic approach provides us with the flexibility to support our clinical and commercial production needs, address time or capacity constraints as well as provide supply redundancy, where appropriate.

Our T-cell product candidates require blood-derived starting materials which are received from healthy, consenting third-party donors through FDA- and EMA-compliant collection centers. Our manufacturing operations are conducted under Code of Federal Regulations Good Manufacturing Practices (GMPs), as well as Good Tissue Practices (GTPs). GTPs are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Through agreements with our partners, we have acquired the right to use certain manufacturing process know-how related to producing clinical research-related drug supply. These include materials to support the manufacturing of clinical study material, including key starting materials and intermediates as well as existing inventory of clinical study materials. We also have the ability to obtain supply from third parties to ensure we have the necessary blood donated from healthy consenting third-party donors.

Human Capital Management

As of December 31, 2020, we had 437 employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. Our human capital strategy is designed to enable successful execution of our business objectives, while fostering a collaborative and innovative culture, that embraces diversity and inclusion. We monitor our success with insights across human capital metrics such as employee engagement, vacancy rates, time to hire, promotion rates, performance ratings, succession depth, retention, EEO compliance, pay equity, and diversity representation. The principal purposes of our compensation policies and equity incentive plans are to attract, retain and motivate employees and directors by paying for performance through the granting of stock-based compensation awards and cash-based performance bonus awards. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we consider our relations with our employees to be good.

COVID-19 Business Update

We continue to closely monitor the impact of the ongoing COVID-19 pandemic on our business and operations and have taken steps to ensure the health and safety of our employees, staff, clinical site staff and patients and to maintain business continuity. Based on guidance issued by federal, state and local authorities, we have temporarily transitioned most of our workforce to a remote, work-from-home model, while maintaining essential in-person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. We implemented safety protocols and procedures to support our onsite workforce.

In addition to implementing measures to protect the health and safety of ourworkforce, our clinical study and operational teams are working closely with clinical sites to ensure the safety of site staff and patients as well as preserve data integrity and access to treatment as appropriate. Where needed, remote study visits, leveraged tele-medicine, home health care, and other methods have been established to ensure continuity of care for patients while preserving key endpoint data.

To date, the COVID-19 pandemic has not materially impacted our or our partners' clinical, research and development, regulatory and manufacturing operations or timelines. We have experienced, and may continue to experience, some transient delays in clinical trial site initiation and patient enrollment in certain of our clinical trials as a result of the evolving impact of the ongoing COVID-19 pandemic. For example, due to the COVID-19 pandemic, in April 2020 we temporarily paused the screening and enrollment of patients in our RCT for ATA188. We were able to resume such activities and enrolled the first patient in the study in June 2020. Our Phase 2 multi-cohort study of tab-cel® has experienced some delays in clinical trial site initiation activities, but we do not believe this study has been significantly impacted. Our Phase 3 clinical trial of tab-cel® in patients with EBV+ PTLD has not been significantly impacted by the ongoing COVID-19 pandemic.

The full extent to which the COVID-19 pandemic may impact our business and operations is subject to future developments which are uncertain and difficult to predict. Further quarantines, shelter-in-place or similar restrictions and other actions taken or imposed by foreign, federal, state and local governments could adversely impact our or our partners' clinical, research and development, regulatory and manufacturing operations or timelines. We continue to monitor the impact of the COVID-19 pandemic on our business and operations and will seek to adjust our activities as appropriate. In addition, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect the financial resources available to us.

For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and operations, see the section titled "1A. Risk Factors" under Part I, Item 1A in this Annual Report on Form 10-K.

Corporate Information

We were incorporated in Delaware in 2012. Our principal corporate offices are located at 611 Gateway Blvd., Suite 900, South San Francisco, California 94080 and our telephone number at that address is (650) 278-8930. Our website address is www.atarabio.com.

Available Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other materials with the Securities and Exchange Commission (SEC). We make these reports available free of charge through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the SEC.

The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risks. Investors should carefully consider all of the risk factors and uncertainties described below, in addition to the other information contained in this Annual Report on Form 10-K, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, before investing in our securities.

The risks described below may not be the only ones relating to our company and additional risks that we currently believe are immaterial may also affect us. If any of these risks, including those described below, materialize, our business, competitive position, reputation, financial condition, results of operations, cash flows and future prospects could be seriously harmed. In these circumstances, the market price of our securities could decline, and investors may lose all or a part of their investment.

Risks Related to Our Financial Results and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that product candidates will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the year ended December 31, 2020, we reported a net loss of $306.6 million.

We do not expect to generate product revenues in the near future, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, in-license or develop, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fails in clinical studies or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that our expenses will increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates and expand our manufacturing and commercialization activities.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our company was formed in August 2012. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical studies, obtain regulatory approval, consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates. In addition, the adoptive immunotherapy technology underlying our T-cell product candidates, including our next-generation CAR T programs, is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be as accurate as they could be if we had a longer operating history or approved products on the market.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Because of the anticipated completion of our BLA filing for tab-cel® in the third quarter of 2021 and a potential approval decision on the same in the first half of 2022, we plan to begin transitioning 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 expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

We currently have no approved products and thus have no product revenues. We may never generate revenues from the sale of products or achieve profitability.

To date, we have not generated any revenues from product sales. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues from product sales or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including any of our current product candidates, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues from the sale of products and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical studies with positive results;
- complete and submit regulatory submissions to the FDA, EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- develop manufacturing and distribution processes for our novel T-cell immunotherapy product candidates;
- develop commercial quantities of our products at acceptable cost levels;
- establish and maintain adequate supply of our products, including cell lines with sufficient breadth to treat patients;
- establish and maintain manufacturing relationships with reliable third parties or qualify our manufacturing facility such that we can maintain the supply of our products by ensuring adequate, manufacturing of bulk drug substances and drug products in a manner that is compliant with global legal requirements;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice, treatment guidelines or a reduction in the incidence of the addressable disease, we may not generate significant revenues from sales of our products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require substantial additional financing to achieve our goals, and 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 expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our T-cell immunotherapy product candidates, and the advancement and expansion of our preclinical research pipeline. We also expect to continue to expend resources for the development and manufacturing of product candidates and the technology we have licensed or have an exclusive right to license from our partners. These expenditures will include costs associated with research and development, potentially acquiring or licensing new product candidates or technologies, conducting preclinical and clinical studies and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of our license agreements with each of our in-license partners, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize on our own. In addition, other unanticipated costs may arise. Because the design and outcome of our ongoing, planned and anticipated clinical studies is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates, if clinical studies are successful, including any costs from post-market requirements;
- the cost of commercialization activities for our product candidates, if any of these product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates for clinical studies in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to develop, acquire or in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing technologies or other adverse market developments.

We believe that our existing cash, cash equivalents and short-term investments as of December 31, 2020, together with projected revenues from U.S. tab-cel® sales, if approved, will be sufficient to fund our operations into 2023, including expenses related to the BLA filing and potential commercial launch of tab-cel® in the U.S. As of December 31, 2020, we had total cash, cash equivalents and short-term investments of $500.7 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We do not have any committed external source of funds other than reimbursements, milestone and royalty payments that we may receive under the Bayer License Agreement. While we expect to continue to opportunistically seek access to additional fundsthrough additional public or private equity offerings or debt financings, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing, additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of our common stock, resulting from the ongoing COVID-19 pandemic. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us.

We may seek required additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or if existing holders of warrants exercise their rights to purchase common stock, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions and uncertainty concerning the COVID-19 pandemic or other factors, the potential magnitude of this dilution will increase. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses or other rights on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business.

Risks Related to the Development of Our Product Candidates

We are generally early in our development efforts and have only a small number of product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be materially harmed.

We are generally early in our development efforts, and only a small number of our product candidates are in clinical development. The majority of our product candidates are currently in preclinical development. We have invested substantial resources in identifying and developing potential product candidates, conducting preclinical and clinical studies, manufacturing activities and preparing for the potential commercial launch of our product candidates. Our ability to generate revenues from the sale of products, if approved, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on many factors, including the following:

- completion of preclinical and clinical studies with positive results;
- receipt of regulatory approvals from applicable authorities;
- protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing or making arrangements with third-party manufacturers or completing our own manufacturing facility for clinical and commercial manufacturing purposes;
- developing manufacturing and distribution processes for our novel T-cell product candidates and next-generation CAR T programs;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other therapies;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

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

Our business and operations have been affected by and could be materially and adversely affected in the future by the effects of health epidemics and pandemics, including the evolving and ongoing effects of the COVID-19 pandemic. The COVID-19 pandemic continues to impact our business and operations and could materially and adversely affect our business and operations in the future, as well as the businesses and operations of third parties on which we rely.

Our business could be adversely affected by health epidemics and pandemics, including the ongoing COVID-19 pandemic, which has presented a substantial public health and economic challenge around the world and has affected, and continues to affect, our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The COVID-19 pandemic has resulted in transient, episodic travel and other restrictions to reduce the spread of the disease and included a California executive order and many other foreign, state and local orders (including in locations where we operate facilities), which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings and order cessation of non-essential travel. As a result of the ongoing COVID-19 pandemic, the work-from-home model we implemented for most of our employees remains in place. We continue to maintain essential in-person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. In connection with these measures, we may be subject to claims based upon, arising out of, or related to COVID-19 and our actions and responses thereto, including any determinations that we may make to continue to operate or to re-open our facilities where permitted by applicable law. The effects of current and potential future state executive orders, local shelter-in-place orders, government-imposed quarantines and our work-from-home policies and other similar, and perhaps more severe, actions 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.

Further quarantines, shelter-in-place or similar restrictions and other actions taken by foreign, federal, state and local governments, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur or could be reinstated, related to the ongoing COVID-19 pandemic or other infectious diseases, could impact our manufacturing capabilities and third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, standard transportation channels have been impacted and we and other manufacturing, testing, product disposition, contract manufacturing organizations and external testing laboratories are subject to enhanced risk assessment and mitigation measures. In addition, there have been and may continue to be interruptions in the supply of leukapheresis collections, which supply raw materials used in our products. Our clinical trials may be affected by health epidemics and have been affected by the ongoing COVID-19 pandemic. Clinical site initiation and patient enrollment have experienced delays as a result of the ongoing COVID-19 pandemic, including due to the prioritization of hospital resources toward COVID-19 and away from clinical trials or as a result of changing practice patterns that impact the diseases our trials address. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services or if patients contract COVID-19 or are forced to quarantine. For example, while most clinical trial sites for our studies, including our Phase 3 clinical trial of tab-cel® in patients with EBV+ PTLD, remain open to enrollment for patients, some sites have limited the screening and enrollment of new patients due to governmental orders related to COVID-19, or fear of infection of COVID-19, have limited, and may continue to limit, patients' abilities to access clinical sites. COVID-19-related travel restrictions may also interrupt key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses. At the outset of the COVID-19 pandemic, we observed a temporary slow-down in stem cell and solid organ transplant volumes, which may have decreased the eligible patient population for the tab-cel® Phase 3 study. In April 2020, we initiated a temporary pause in the screening and enrollment of patients in our RCT of ATA188 in patients with progressive MS. Although we were able to resume the screening and enrollment of patients in our RCT of ATA188and enrolled the first patient in the study in June 2020, the ongoing COVID-19 pandemic may require us to institute another pause in the screening and enrollment of patients in our RCT. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be adversely impacted.

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic and the various actions taken in response to it may be difficult to assess or predict, the pandemic could result in significant disruption of global financial markets, reducing 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.

While we expect the ongoing COVID-19 pandemic to continue to adversely affect our business operations, the extent of the impact on our clinical development and regulatory efforts and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of the ongoing COVID-19 pandemic adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

Our future success is dependent on the regulatory approval of our product candidates.

We do not have any products that have gained regulatory approval. Currently, our prioritized clinical-stage product candidates include tab-cel®, for which we are positioned to initiate a BLA submission to the FDA for EBV+ PTLD, and ATA188. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner.

We cannot commercialize product candidates in the U.S. without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical and clinical studies 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. We have not obtained regulatory approval for any product candidate and 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 a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical studies;
- failure to demonstrate positive benefit/risk profile of the product candidate for its proposed indication;
- failure of clinical studies to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical studies;
- the insufficiency of data collected from clinical studies of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, 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.

In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates, such as our novel T-cell product candidates and next-generation CAR T programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EMA and FDA for existing autologous CAR T therapies, such as Novartis's Kymriah® and Gilead's Yescarta®, may not be indicative of what these regulators may require for approval of our therapies. Moreover, our product candidates may not perform successfully in clinical studies or may be associated with adverse events that distinguish them from those that have previously been approved, such as existing autologous CAR T therapies. For instance, allogeneic product candidates may result in adverse events not experienced with autologous products.

Our development and commercialization activities could be harmed or delayed by governmental or regulatory delays due to limitations on the availability of governmental and regulatory agency personnel to review regulatory filings or engage with us, as a result of the COVID-19 pandemic, changes to governmental regulatory requirements, policies, guidelines or priorities, reallocation, or availability of government resources, or for other reasons, which may significantly delay the FDA's, or other regulatory agency, ability to review and process any submissions we have filed or may file or cause other regulatory delays.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, 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 T-cell immunotherapy product candidates and our next-generation CAR T programs represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.

Our future success is dependent on the successful development of T-cell immunotherapies and our next-generation CAR T programs in general and our development product candidates in particular. Because these programs, particularly our pipeline of allogeneic T-cell product candidates that are bioengineered from donors, represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of T-cell immunotherapies, particularly allogeneic T-cell product candidates;
- developing and deploying consistent and reliable processes for procuring blood from consenting third-party donors, isolating T cells from the blood of such donors, activating the isolated T cells against a specific antigen, characterizing and storing the resulting activated T cells for future therapeutic use, selecting and delivering a sufficient supply and breadth of appropriate partially HLA-matched cell line from among the available T-cell lines, and finally infusing these activated T cells into patients;

- utilizing these product candidates in combination with other therapies (e.g., immunomodulatory approaches such as checkpoint inhibitors), which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of each of our product candidates, particularly those that may be unique to our allogeneic T-cell product candidates and to our next-generation CAR T programs;
- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to manufacture product in a reliable and consistent manner;
- developing processes for the safe administration of these products, including long-term follow-up and registries, for all patients who receive these product candidates;
- manufacturing our product candidates to our specifications and in a timely manner to support our clinical studies and, if approved, commercialization;
- sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process these product candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities ahead of and after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of diseases beyond those initially addressed by our current product candidates.

We cannot be sure that the manufacturing processes used in connection with our T-cell immunotherapy product candidates will yield a sufficient supply of satisfactory products that are safe, pure, potent, comparable to those T cells produced by our partners historically, scalable or profitable.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical studies, or, if one of our product candidates is approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics or of patients to provide consent to receive a novel treatment despite its regulatory approval. The FDA or other applicable regulatory authorities may require specific post-market studies or additional information that communicates the benefits or risks of our products. New data may reveal new risks of our product candidates at any time prior to or after regulatory approval.

Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training or not cost-efficient, and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

The results of preclinical studies or earlier clinical studies are not necessarily predictive of future results. Our existing product candidates in clinical studies, and any other product candidate we advance into clinical studies, may not have favorable results in later clinical studies or receive regulatory approval.

Success in preclinical studies and early clinical studies does not ensure that later clinical studies will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical studies, even after seeing promising results in earlier preclinical studies or clinical studies. Despite the results reported in earlier preclinical studies or clinical studies for our product candidates, we do not know whether the clinical studies we may conduct, or clinical studies in progress, will demonstrate adequate efficacy and safety to result in regulatory approval to market tab-cel®, ATA188, any product candidates resulting from our next-generation CAR T programs or any of our other product candidates in any particular jurisdiction.

Tab-cel® has been predominantly evaluated in single-center studies under investigator-sponsored INDs held by MSK and in our EAP, utilizing different response criteria and endpoints from those we may utilize in later clinical studies. The findings may not be reproducible in late phase studies we conduct. For instance, the current protocol for our ALLELE study is designed to rule out a 20% ORR as the null hypothesis. This means that if the lower bound of the 95% confidence interval on ORR among patients receiving at least one dose of tab-cel® exceeds 20% at the end of the study, then the study would be expected to meet the primary endpoint for the treatment of PTLD. For example, assuming enrollment of 33 patients in a cohort of ALLELE, an observed ORR above approximately 37% would be expected to meet the primary endpoint for that cohort. In addition, our amended ALLELE study protocol includes an interim analysis as well as a final study analysis. Depending on discussions with regulators, we may, for example, file a marketing application on the basis of interim data from a subset of the required patients or file a marketing application on the basis of the final data. A marketing application based on interim data would impact the required ORR and may also result in post-marketing requirements that must be fulfilled. Similarly, if conditional marketing authorization is granted from the European Commission, we may be subject to ongoing obligations, including the need to provide additional clinical data at a later stage to confirm a positive benefit/risk balance.

For regulatory approvals of tab-cel®, we plan on using independent radiologist and/or oncologist assessment of responses which may not correlate with the investigator-reported assessments. In addition, the Phase 2 clinical studies with tab-cel® enrolled a heterogeneous group of patients with a variety of EBV-driven malignancies, including EBV+ PTLD after HCT and EBV+ PTLD after SOT. These Phase 2 studies were not prospectively designed to evaluate the efficacy oftab-cel® in the treatment of a single disease state for which we may later seek approval.

Moreover, final study results may not be consistent with interim study results. Efficacy data from prospectively designed studies may differ significantly from those obtained from retrospective subgroup analyses. In addition, clinical data obtained from a clinical study with an allogeneic product candidate may not yield the same or better results as compared to an autologous product candidate. If later-stage clinical studies do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical studies.

Interim "top line" and preliminary data from clinical studies that we or our partners may announce or share with regulatory authorities from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we or our partners may announce or share with regulatory authoritiesinterim "top line" or preliminary data from clinical studies. Interim data from completed clinical studies 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. Preliminary or "top line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously announced. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could impact the regulatory approval of, and significantly harm the prospects of any product candidate that is impacted by the applicable data.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical and clinical studies.

We may experience delays in our ongoing or future clinical studies and we do not know whether clinical studies will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical studies of any of our product candidates on clinical hold in the future. Clinical studies may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delays in enrollment due to travel, shelter-in-place or quarantine policies, or other factors, related to the ongoing COVID-19 pandemic or other epidemics or pandemics;
- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a study design that we are able to execute;
- delay or failure in obtaining authorization to commence a study or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a study;

- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical study at each site;
- withdrawal of clinical study sites from our clinical studies or the ineligibility of a site to participate in our clinical studies;
- delay or failure in recruiting and enrolling eligible subjects to participate in a study;
- delay or failure in subjects completing a study or returning for post-treatment follow-up;
- clinical sites and investigators deviating from study protocol, failing to conduct the study in accordance with regulatory requirements, or dropping out of a study;
- an FDA or other regulatory authority clinical site inspection reveals serious violations of regulations applicable to clinical investigations, which may result in requests for additional data analyses and/or rejection of data deemed unreliable;
- inability to identify and maintain a sufficient number of study sites, including because potential study sites may already be engaged in competing clinical study programs enrolling the same population;
- failure of our third-party clinical study managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new study sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol for a study;
- a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical studies at any time for safety issues or for any other reason;
- unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing or obtaining from third parties sufficient quantities and breadth of appropriate partially HLA matched cell lines from among the available T-cell lines to start or to use in clinical studies;
- lack of adequate funding to continue a study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical study.

Patient enrollment, a significant factor in the timing of clinical studies, is affected by many factors including:

- the size and nature of the patient population;
- the possibility that the rare diseases that many of our product candidates address are under-diagnosed;
- changing medical practice patterns or guidelines related to the diseases or conditions we are investigating;
- the severity of the disease under investigation, our ability to open clinical study sites;
- the proximity of subjects to clinical sites;
- the patient referral practices of physicians;
- the design and eligibility criteria of the clinical study;
- ability to obtain and maintain patient consents;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical studies;

- our or our partner's ability to manufacture the requisite materials for a study;
- risk that we do not have appropriately matched HLA cell lines;
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the diseases or conditions we are investigating; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the ongoing COVID-19 pandemic.

As an example, we activated additional clinical sites over the course of 2018 and increased HLA coverage during this period. As a result, enrollment in our studies was limited in the early part of 2018 and increased through the course of the year as we increased clinical sites and HLA coverage. However, in May 2019, we announced that enrollment in our Phase 3 studies of tab-cel® for patients with EBV+ PTLD was proceeding slower than anticipated. Many of our product candidates are designed to treat rare diseases, and as a result, the pool of potential patients with respect to a given disease is small. We may not be able to initiate or continue to support clinical studies of tab-cel®, ATA188 or any other product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies as required by the FDA or other regulatory authorities. We have experienced some transient delays in clinical trial site initiation and patient enrollment in certain of our clinical trials, including our Phase 3 clinical trial of tab-cel®, as a result of the evolving impact of the ongoing COVID-19 pandemic, and if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timelines. Even if we are able to enroll a sufficient number of patients in our clinical studies, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete.

We rely on CROs, other vendors and clinical study sites to ensure the proper and timely conduct of our clinical studies, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Reliance on CROs entails risks to which we would not be subject if we conducted our clinical studies ourselves, including reliance on the CRO for clinical site initiation and monitoring, the possibility that the CRO does not maintain the financial resources to meet its obligations under our agreements, the possibility of breach of these agreements by the CRO because of factors beyond our control, including a failure to properly perform their obligations under these agreements, and the possibility of termination or nonrenewal of the agreements by the CROs, based on their own business priorities, at a time that is costly or damaging to us.

If we experience delays or quality issues in the conduct, completion or termination of any clinical study of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical studies will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. In addition, many of the factors that could cause a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we or our partners may experience in our clinical studies, we or our partners may not receive approval to market any product candidates, which could prevent us from ever generating product or royalty revenues or achieving profitability. Results of our studies could reveal an unacceptably high severity and incidence of side effects, or risks that outweigh the benefits of our product candidates. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the study or result in potential product liability claims.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of that product;
- regulatory authorities may withdraw or change their approvals of that product;

- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

The FDA often approves new cancer therapies initially only for use in patients with relapsed or refractory metastatic disease. We expect to initially seek approval of tab-cel® and our other product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy, and who have the potential to benefit from treatment with our product candidates, are based on our current beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or our own market research, and may prove to be incorrect, including if the COVID-19 pandemic and associated responses impact our ability to engage with key stakeholders within the transplant center in person. Further, new studies or market research may change the estimated incidence or prevalence of these diseases, and the number of patients may turn out to be lower 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. For instance, we expect our lead product candidate, tab-cel®, to initially target a small patient population that suffers from aggressive EBV+PTLD who have failed rituximab or rituximab plus chemotherapy. At the outset of the COVID-19 pandemic, we initially observed a temporary slow-down in stem cell and solid organ transplant volumes. These reductions were transient, but if a reduction in such volumes resumes, it could result in lower PTLD incidence and thus reduce the demand for tab-cel®. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the U.S., EU and the United Kingdom (U.K.), may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. Both the FDA and the EMA have granted us orphan designation for tab-cel® for EBV+ PTLD after HCT or SOT.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same biologic for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not be maintained or effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a new drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

BTD by the FDA and PRIME designation by the EMA may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

Although we have obtained BTD and PRIME designation for tab-cel® for EBV+ PTLD in the U.S. and the EU, respectively, this may not lead to faster development or regulatory review and does not increase our likelihood of success. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the study can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review. Based on our BTD, we intend to pursue a rolling submission strategy for our BLA for tab-cel® for EBV+ PTLD in the U.S. While the rolling review process may provide the opportunity for ongoing communications with and feedback from the FDA, the FDA may raise issues and pose questions to us that may delay the initiation and completion of our BLA submission, acceptance of the complete BLA for filing, and approval of the BLA, thereby potentially delaying the approval process. We may not be able to provide a satisfactory or a timely response to FDA questions or we may not be able to timely gather the required data to prepare our BLA submissions as we plan. If we are unable to address all questions or concerns the FDA may raise or if we do not have timely access to the data required for the preparation of the BLA, we may not be able to timely initiate and complete our BLA and ultimately receive FDA approval. In addition, the FDA retains discretion to decide not to review the portions of our BLA submitted under the rolling review process until the submission is deemed to be complete.

PRIME designation supports the development and accelerated review by the EMA of new therapies to treat patients with unmet medical need.

Designation as a breakthrough therapy is within the discretion of the FDA, and access to PRIME is at the discretion of the EMA. Receipt of a BTD or PRIME designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA or EMA review procedures, respectively, and does not assure ultimate approval by the FDA or EMA, respectively. In addition, the FDA or EMA, respectively, may later decide that the product no longer meets the conditions for qualification and rescind the BTD or PRIME designation or decide that the time period for FDA or EMA, respectively, review or approval will not be shortened.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the U.S., to market and sell our products in the EU, the U.K., many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. Clinical studies accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U.S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, the U.K., Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our contract manufacturing organizations (CMOs) and CROs for any post-approval clinical studies that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (cGMP), current Good Clinical Practices (GCP), current good tissue practices (cGTP) and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products.

Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice (the DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. will be heavily scrutinized by comparable foreign entities and stakeholders. For example, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

Regulations, guidelines and recommendations published by various government agencies and organizations may affect the use of our product candidates.

Changes to regulations, recommendations or other guidelines advocating alternative therapies for the indications we treat could result in decreased use of our products. For example, although treatment with EBV-specific T cells is recognized as a recommended treatment for persistent or progressive EBV+ PTLD as set forth in the 2017 National Comprehensive Cancer Network Guidelines, future guidelines from governmental agencies, professional societies, practice management groups, private health/science foundations and other organizations could lead to decreased ability of developing our product candidates, or decreased use of our products once approved by applicable regulatory authorities.

We may not successfully identify, acquire, develop or commercialize new potential product candidates.

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them.

Bayer is generally responsible for the conduct and funding of the development and commercialization of ATA2271 and ATA3271.

Pursuant to the Bayer License Agreement, Bayer holds an exclusive, field-limited license to ATA2271 and ATA3271. As a result, other than the development of ATA2271 through Phase 1, Bayer is generally responsible for the development and obtaining and maintaining regulatory approval of ATA2271 and ATA3271.

We do not control the development activities being conducted or that may be conducted in the future by Bayer, including, but not limited to, the timing of initiation, termination or completion of clinical trials, the analysis of data arising out of those clinical trials or the timing of release of data concerning those clinical trials, which may impact our ability to report on Bayer's results. Bayer may conduct these activities more slowly or in a different manner than we would if we controlled the development of ATA2271 after Phase 1 and ATA3271. Bayer is responsible for submitting future applications to the FDA and other regulatory authorities for approval of ATA2271 and ATA3271 and will be the owner of marketing approvals issued by the FDA and other regulatory authorities for ATA2271 and ATA3271, if approved. If the FDA or other regulatory authorities approve ATA2271 and/or ATA3271, Bayer will also be responsible for the marketing and sale of the resulting product. However, we cannot control whether Bayer will devote sufficient attention and resources to the development of ATA2271 and/or ATA3271 or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve ATA2271 and/or ATA3271, Bayer may elect not to proceed with the commercialization of the resulting product in one or more countries.

We are currently negotiating a separate manufacturing and supply agreement with Bayer for the supply of allogenic mesothelin-directed CAR T-cell therapies for clinical trials. Delays in the negotiation and execution of this manufacturing and supply agreement would result in a delay in the ATA2271 and/or ATA3271 programs and would delay and could prevent us from obtaining revenues for this product candidate.

Disputes may arise between us and Bayer, which may delay or cause the termination of any clinical trials of ATA2271 and/or ATA3271, result in significant litigation or cause Bayer to act in a manner that is not in our best interest. The costs associated with the continuing development of ATA2271 and/or ATA3271 may cause Bayer to reconsider the terms of its investment and seek to amend or terminate our agreement or to suspend the development of ATA2271 and/or ATA3271. If development of ATA2271 and/or ATA3271 does not progress for these or any other reasons, we would not receive milestone payments or royalties on product sales from Bayer with respect to ATA2271 and/or ATA3271. If the results of one or more clinical trials with ATA2271 and/or ATA3271 do not meet Bayer's expectations at any time, Bayer may elect to terminate further development of ATA2271 and/or ATA3271 or certain of the potential clinical trials for ATA2271 and/or ATA3271, even if the actual number of patients treated at that time is relatively small. In addition, Bayer generally has discretion to elect whether to pursue or abandon the development of ATA2271 and/or ATA3271 and may terminate our strategic alliance in whole or on a product-by-product basis for any reason upon 120 days prior notice. If Bayer abandons ATA2271 and/or ATA3271, it would result in a delay in or could prevent us from commercializing ATA2271 and/or ATA3271 and would delay and could prevent us from obtaining revenues for this product candidate.

If Bayer abandons development of ATA2271 and/or ATA3271 prior to regulatory approval or if it elects not to proceed with commercialization of the resulting product following regulatory approval, we would have to seek a new partner for development or commercialization, curtail or abandon that development or commercialization, or undertake and fund the development of ATA2271 and/or ATA3271 or commercialization of the resulting product ourselves. If we seek a new partner but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of ATA2271 and/or ATA3271 ourselves, we would have to curtail or abandon that development or commercialization, which could harm our business.

We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses.

We may desire to form additional strategic alliances, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or business, in each case that we believe will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive benefit/risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

Risks Related to Manufacturing

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

Concurrently with the in-license of our existing product candidates, we acquired manufacturing process know-how and, in some cases, inventory of process intermediates and clinical materials from our partners. Transferring manufacturing processes, testing and associated know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. Each stage is retroactively and concurrently verified to be compliant with appropriate regulations. As a result, there is a risk that all relevant know-how was not adequately transferred to us from our partners or that previous execution was not compliant with applicable regulations.

In addition, we need to conduct significant development and scale-up work to transfer these processes and manufacture each of our product candidates for various studies, clinical studies and commercial launch readiness. To the extent we elect to transfer manufacturing within our network, we are required to demonstrate that the product manufactured in the new or "receiving" facility is comparable to the product manufactured in the original or "sending" facility. The inability to demonstrate to each of the applicable regulatory authorities that comparable drug product was manufactured could delay the development of our product candidates.

The processes by which our product candidates are manufactured were initially developed by our partners for clinical purposes. We intend to evolve the existing processes with our partners to support advanced clinical studies and commercialization requirements. Developing commercially viable manufacturing processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical studies or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by the ongoing COVID-19 pandemic, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors. In addition, there have been, and there may continue to be, interruptions in the supply of leukapheresis collections related to the COVID-19 pandemic, which supply raw materials used in our product candidates. If we are unable to obtain such raw materials or other necessary raw materials in a timely manner, our business operations and manufacturing capabilities could be adversely affected.

The process of manufacturing cellular therapies is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, impact to key product quality attributes, and other supply disruptions. Product defects can also occur unexpectedly. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our T-cell immunotherapy product candidates are manufactured from the blood of third-party donors, the process of manufacturing is susceptible to the availability of the third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. This type of contaminations could result in delays in the manufacture of products which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects. Furthermore, our allogeneic products ultimately consist of many individual cell lines, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell line for therapeutic use in a patient requires close coordination between clinical operations, supply chain and quality assurance personnel.

Any adverse developments affecting manufacturing operations for our product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the supply of our drug product which could delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

We intend to manufacture a majority of our product candidates ourselves. Delays in receiving regulatory approvals for product candidates produced in our manufacturing facility could delay our development plans and thereby limit our ability to generate revenues.

The research and development and process and analytical development labs within our manufacturing facility in Thousand Oaks, California are currently supporting preclinical development activities. The facility commissioning and qualification activities required to support production at our facility were completed in 2018. Product-specific qualification to support clinical development is complete and commercial production qualification activities are ongoing. If the appropriate regulatory approvals for manufacturing product candidates in our facility are delayed, we may not be able to manufacture sufficient quantities of our product candidates, which would limit our development activities and our opportunities for growth.

In addition to the similar manufacturing risks described in "Risks Related to Our Dependence on Third Parties," our manufacturing facility will be subject to ongoing, periodic inspection by the FDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP and GTP. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical study, or may delay or prevent filing or approval of commercial marketing applications for our product candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical studies, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facility. Without further investment, advances in manufacturing techniques may render our facility and equipment inadequate or obsolete.

A number of the product candidates in our portfolio, if approvedby applicable regulatory authorities, may require significant commercial supply to meet market demand. In these cases, we may need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our product candidates in a sufficient quantity to meet future demand.

If our sole clinical or commercial manufacturing facility or our CMO is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.

If any manufacturing facility in our manufacturing network, or the equipment in these facilities, is either damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of a facility or its equipment, we may not be able to transfer manufacturing to a third party in the time required to maintain supply. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements or may require regulatory approval before selling any products manufactured at that facility. Such an event could delay our clinical studies or reduce our commercial product sales.

Currently, we maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

Risks Related to Our Dependence on Third Parties

Maintaining clinical and commercial timelines is dependent on our end-to-end supply chain network to support manufacturing; if we experience problems with our third party suppliers we may delay development and/or commercialization of our product candidates.

We rely in part on our CMOs or our partners for the current production of our product candidates and the acquisition of materials incorporated in or used in the manufacturing or testing of our product candidates. Our CMOs or partners are not our employees, and except for remedies available to us under our agreements with our CMOs or partners, we cannot directly control whether or not they devote sufficient time and resources, including experienced staff, to the manufacturing of supply for our ongoing clinical, nonclinical and preclinical programs. Our CMOs for tab-cel® will need to be prepared to undergo pre-approval inspection in connection with our anticipated BLA, and we cannot be certain that we will be able to adequately support them through such inspection nor that they will successfully pass any such inspection.

To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tab-cel®, ATA188, any product candidates resulting from our next-generation CAR T programs or any other product candidates, we will need to transition the manufacturing of these materials to a CMO or our own facility. Regardless of where production occurs, we will need to develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability of the material produced at these facilities to the material that was previously produced. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time.

In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We would expect additional comparability work will also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data has been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced with that generated by our CMO.

If we are not able to successfully transfer and produce comparable product candidates, our ability to further develop and manufacture our product candidates may be negatively impacted.

While our manufacturing facility in Thousand Oaks, California provides us with flexibility within our manufacturing network, we still may need to identify additional CMOs for continued production of supply for some of our product candidates. Given the nature of our manufacturing processes, the number of CMOs who possess the requisite skill and capability to manufacture our T-cell immunotherapy product candidates is limited. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them.

Manufacturing cellular therapies is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product candidate or intermediate would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our product candidates at costs, or in sufficient quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA or comparable regulatory authorities not agree with our product candidate specifications and comparability assessments for these materials, further clinical development of our product candidate could be substantially delayed and we would incur substantial additional expenses.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar regulatory jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretations and enforcement of existing standards for manufacture,

packaging or testing of products. We have limited control over our manufacturers' compliance with these regulations and standardsand although we monitor our manufacturers, we depend on them to provide honest and accurate information. Any failure by our third-party manufacturers to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical studies, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

We depend on third party suppliers for key materials used to produce our product candidates. Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate for an ongoing clinical study could considerably delay initiation or completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If raw materials or components cannot be purchased or fail to meet approved specifications, the commercial launch of our product candidates could be delayed, or there could be a shortage in supply, which could impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements – both that we own or possess or that are owned or possessed by our partners that are in-licensed to us – to protect the intellectual property related to our technology and product candidates. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. For example, the product candidates and platform technology we have licensed from our partners are protected primarily by patent or patent applications of our partners that we have licensed and as confidential know-how and trade secrets. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office (USPTO) and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the U.S. or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in these patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek a license from a third party who owns intellectual property that may be useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all.

In addition, 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.

We and our partners have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product candidate. We or our partners may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and *inter partes* and post-grant review proceedings before the USPTO the European Patent Office and other non-U.S. patent offices.

Even if granted, patents have a limited lifespan. In the U.S., the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical studies or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates.

Furthermore, the research resulting in certain of our licensed patent rights and technology was funded by the U.S. government. As a result, the government has certain rights to these patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to practice the invention for or on behalf of the U.S. These rights may permit the government to disclose confidential information on which we rely to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our rights in any inventions that result from government-funded research may be subject to certain requirements to manufacture products embodying these inventions in the U.S.

If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and *inter partes* and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims.

If we or our partners are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expired. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates.

Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. In the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any of these license agreements may require us to pay royalties and other fees that could be significant. As a result of all of the foregoing, any actual or threatened intellectual property claim could prevent us from developing or commercializing a product candidate or force us to cease some aspect of our business operations.

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

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the U.S. may be less extensive than those in the U.S. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the U.S. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the U.S., or from selling or importing infringing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the U.S. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

We have in-licensed a significant portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates.

We hold rights under license agreements with our partners, including MSK, QIMR Berghofer and Moffitt that are important to our business. Our discovery and development platform is built, in part, around patent rights in-licensed from our partners. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners would materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates and our ability to commercialize the affected product candidates. Furthermore, a disagreement under any of these license agreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual property rights, to protect our or our partners' trade secrets or to determine the validity or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid.

Interference or derivation proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non-U.S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, *inter partes* review, post-grant review or other pre-issuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can. Accordingly, despite our or our partners' efforts, we or our partners may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the U.S. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. The T-cell immunotherapy product candidates and platform technology we have licensed from our partners are protected primarily as confidential know-how and trade secrets. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the U.S. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidates as demonstrated in clinical studies;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians and patients of the drug as a safe and effective treatment;
- the administrative and logistical burden of treating patients;
- the adoption of novel cellular therapies by physicians, hospitals and third-party payors;

- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. In some countries such as the U.S., greater cost-shifting from the payor to the patient is also a trend, and higher patient copayments or other administrative burdens could lead to reduced demand from patients or healthcare professionals. This could particularly be the case in a challenging economic climate, such as during the ongoing COVID-19 pandemic. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval, and ultimately our ability to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the U.S. Third-party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Current and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research and established a new Medicare Part D coverage gap discount program.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. 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, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021, and extended the sequester by one year, through 2030. In January 2013, the American Taxpayer Relief Act of 2012 (the ATRA) was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There remain judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, President Trump signed Executive Orders designed to delay or eliminate the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, eliminating the implementation of certain mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In December 2018, a Texas District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the Tax Act). In December 2019, the U.S. Court of Appeals for the 5th Circuit upheld the Texas District Court ruling that the individual mandate was unconstitutional and remanded the case back to the Texas District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the United States Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the United States Supreme Court ruling, other such litigation, and the healthcare form measures of the Biden administration will impact the Affordable Care Act and our business.

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. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the U.S. or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product candidates, if any, may be. In the U.S., the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. For example, in the U.S., there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for the fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. In March 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, in May 2018, the Trump administration previously laid out a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. 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 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. Further, on November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented 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, to encourage importation from other countries and bulk purchasing. Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our collaborators, may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Additionally, our commercial opportunities will be reduced or eliminated if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of our current or future target diseases. Competition could result in reduced sales and pricing pressure on our product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

There are currently no FDA- or EMA-approved products for the treatment ofEBV+ PTLD. However, some marketed products and therapies are used off-label in the treatment of EBV+ PTLD, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing product candidates for EBV+ PTLD and other EBV-driven diseases including: Viracta Therapeutics, Inc., which is conducting a Phase 1b/2 clinical study for nanatinostat (formerly named tractinostat, or VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas; AlloVir (formerly known as ViraCyte), which has completed a Phase 2 clinical study for Viralym-M (ALVR105), an allogeneic, multi-virus T-cell product that targets six viruses in allogeneic HSCT recipients with ≥1 treatment-refractory infection, including EBV, and is planning to initiate several Phase 3 studies for CMV, AdV and Virus-Associated Hemorrhagic-Cystitis, as well as a Phase 1b/2 proof of concept trial for the prevention of BKV, CMV, AdV, EBV, HHV06 and JCV; and Tessa Therapeutics Pte Ltd., which has a Phase 2 autologous and preclinical allogeneic CD30-CAR-T product candidate being evaluated in CD30+ lymphomas.

Competition in the MS market is high with at least 20 therapies, including four generics or bioequivalents, approved in the U.S. and EU for the treatment of various forms of MS, including clinically isolated syndrome, relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS). There are many competitors in the MS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Kesimpta® (anti-CD20 monoclonal antibody), marketed by Novartis, was approved in the U.S. for the treatment of relapsing forms of MS, and a decision for its approval for treatment of the same indication in the EU is expected in the first half of 2021. Johnson & Johnson has completed Phase 3 studies of its sphingosine-1-phosphate receptor 1 (S1P1) modulator, ponesimod, and has sought regulatory approval also for relapsing forms of MS in the U.S. and EU.

There are numerous development candidates in Phase 3 studies for both relapsing and/or progressive forms of MS and additional novel agents could be approved in either or both indications in the future including TG Therapeutics' anti-CD20 monoclonal antibody ublituximab, EMD Serono's Bruton's tyrosine kinase (BTK) inhibitor, evobrutinib, Roche's BTK inhibitor, fenebrutinib, Sanofi's BTK inhibitor, SAR442168 and AB Science's tyrosine kinase inhibitor, masitinib. Medicinova is planning to initiate a Phase 3 study of its PDE inhibitor, ibudilast (MN166) in non-active SPMS.

There are currently four autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel), Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus™ (brexucabtagene autoleucel) and Bristol-Myers Squibb's Breyanzi® (lisocabtagene maraleucel). Bristol-Myers Squibb has filed a BLA to the U.S. FDA for idecabtagene vicleucel with bluebird bio. There are many CAR-mediated cell therapies in development, and, although the majority are autologous, they include allogeneic and off-the-shelf cell therapies. There are multiple allogeneic CAR platforms being developed with differences in approaches to minimize instances of donor cells recognizing the patient's body as foreign or rejection of the donor cells by the patient's body. These approaches include the use of gene-editing to removeor inhibit the TCR and the use of cell types without a TCR. The majority of clinical stage allogeneic CAR programs utilize alpha beta T cells as the cell type and gene editing of the T-cell receptor and HLA as the preferred technology approach, however, other strategies are also in development. It is possible that some of these other approaches will have more favorable characteristics than the approach we utilize, which would result in them being favored by potential partners or customers over our products. Depending on the diseases that we target in the future, we may face competition from both autologous and allogeneic CAR therapies and other modalities (e.g., small molecules, antibodies) in the indication of interest.

Many of the approved or commonly used drugs and therapies for our current or future target diseases, includingEBV+ PTLD and MS, are well established and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. We expect that, if any of our product candidates are approved, they will be priced at a significant premium over competitive generic products. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies or if they are acquired by larger companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

We expect the product candidates we develop will be regulated as biological products (biologics) and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

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

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue from the sale of our products.

We are at an early stage of establishing an organization that will be responsible for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities, or entering into agreements with third parties to market and sell our products, would adversely impact the commercialization of these products. We may be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without a sufficiently scaled, appropriately timed and trained internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

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

As of December 31, 2020, we had 437 employees. We have made the decision to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates. In particular, we may need to add substantial numbers of additional personnel and other resources to support our development and potential commercialization of our product candidates. As our development and commercialization plans and strategies continue to develop, or as a result of any future acquisitions, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources will increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical and clinical studies effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including the additional personnel needed to support continued development and potential commercialization of our product candidates;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

As our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and preclinical and clinical studies effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

Risks Related to Ownership of Our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance.

Our stock price has fluctuated in the past and can be expected to be volatile in the future. From January 1, 2018 through December 31, 2020, the reported sale price of our common stock has fluctuated between $4.52 and $54.45 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In particular, the ongoing COVID-19 pandemic has further heightened the volatility of the stock market for biopharmaceutical companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or products or our competitors' product candidates or products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

- results of clinical studies of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent or unusual trading volume levels of our shares or derivatives thereof;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

In addition, the stock markets in general, and the markets for biotechnology and pharmaceutical stocks in particular, have experienced significant volatility that has often been unrelated to the operating performance of particular companies, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies. For example, negative publicity regarding drug pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the markets for biotechnology and pharmaceutical stocks. Likewise, as a result of significant changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade and healthcare spending and delivery, including the possible repeal and/or replacement of all or portions of the Affordable Care Act or changes in tariffs and other restrictions on free trade stemming from U.S. and foreign government policies, or for other reasons, the financial markets could experience significant volatility that could also negatively impact the markets for biotechnology and pharmaceutical stocks. These market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and divert management's attention and resources, which could result in delays of our clinical studies or commercialization efforts.

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

Our principal stockholders own a significant portion of our outstanding common stock. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. The interests of our significant stockholders may not always coincide with the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We have incurred and will continue to incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Stock Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted and will adopt additional rules and regulations, such as mandatory "say on pay" voting requirements, that now apply to us. Stockholder activism, the current political environment and the potential for future regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time-consuming and costly. To the extent these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of potential gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock in one or more transactions at prices and in a manner we determine from time to time. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options or warrants, and any additional shares issued in connection with acquisitions or in-licenses, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions and uncertainty concerning the COVID-19 pandemic or other factors, the potential magnitude of this dilution will increase. Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, non-employee directors and consultants. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans will result in dilution and may have an adverse effect on the market price of our common stock.

Some terms of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation (Certificate of Incorporation) and amended and restated bylaws (Bylaws), as well as Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include terms that:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms, which makes it more difficult to replace a majority of our directors in a short period of time;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by our board of directors, the chairperson of our board of directors or our chief executive officer.

Any of the factors listed above may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management.

In addition, because we are incorporated in Delaware, we are governed by Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any term of our Certificate of Incorporation or Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us and our business. In the event securities or industry analysts who cover us downgrade our stock or publish unfavorable research about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

General Risk Factors

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our executive officers and other key employees and the loss of the services of any of our executive officers or other key employees, including scientific, technical or management personnel, could impede the achievement of our corporate objectives.

Our success depends on our ability to recruit, retain, manage and motivate our employees. Although we enter into employment agreements or offer letters with our employees, these documents provide for "at-will" employment, which means that any of our employees could leave our employment at any time, with or without notice. Competition for skilled personnel in our industry and geographic regions is intense and may limit our ability to hire and retain qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest over time. The value to employees of equity awards may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, privacy and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with 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 conduct research and would market, sell and distribute our products. As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education 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 here, among other foreign laws. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute, which governs our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by HITECH also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- state and foreign laws and regulations that are analogous to the federal laws and regulations described in the preceding subsections of this risk factor, 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; and
- 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; some state laws require drug manufacturers to report information regarding pricing and marketing information related to payments and other transfers of value to physicians and other healthcare providers; some state and local laws require the registration of pharmaceutical sales representatives; and other state laws require the protection of the privacy and security of health information, which may differ from each other in significant ways and often are not preempted by HIPAA.

Additionally, we may be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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 studies and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical studies, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical study sites or entire study programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical study participants;
- significant costs to defend the related litigation;
- substantial monetary awards to study subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. 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. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

We and our third-party manufacturers 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 or our third-party manufacturers' 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.

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 with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects.

The actual or perceived failure by us, our customers, or vendors to comply with increasingly stringent laws, regulations and contractual obligations relating to privacy, data protection, and data security could harm our reputation, and subject us to significant fines and liability.

We are or may become subject to numerous domestic and foreign laws and regulations regarding privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations and may be inconsistent among countries, or conflict with other rules. We are also subject to the terms of our contractual obligations to customers and third parties related to privacy, data protection, and data security. The actual or perceived failure by us, our customers, our vendors, or other relevant third parties to address or comply with these laws, regulations, and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, cause regulators to reject, limit or disrupt our clinical trial activities, result in reputational harm, lead to a loss of customers, reduce the use of our products, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

For example, the EU adopted GDPR, which imposes onerous and comprehensive privacy, data protection, and data security obligations onto data controllers and processors, including, as applicable, contractual privacy, data protection, and data security commitments, expanded disclosures to data subjects about how their personal information is used, honoring individuals' data protection rights, limitations on retention of personal information, additional requirements pertaining to sensitive information (such as health data) and pseudonymized (i.e., key-coded) data, data breach notification requirements, higher standards for obtaining consent from data subjects, changes to informed consent practices, and more detailed notices for clinical trial subjects and investigators. Penalties for non-compliance with the GDPR can be significant and include fines in the amount of the greater of €20 million or four percent of global turnover and restrictions or prohibitions on data processing, which could impair our ability to do business in the EU, reduce demand for our services and adversely impact our business and results of operations. The GDPR also provides that EU member states may introduce further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share European data, cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices.

European privacy, data protection, and data security laws, including the GDPR, generally restrict the transfer of personal information from the EEA to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. Data protection laws in the U.K. and Switzerland impose similar restrictions. There is uncertainty on how to implement such safeguards and how to conduct such transfers in compliance with the GDPR, and certain safeguards may not be available or applicable with respect to some or all of the personal information processing activities necessary to research, develop and market our products and services. One of the primary safeguards allowing U.S. companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks. However, the EU-U.S. Privacy Shield framework was invalidated in July 2020 in a decision by the Court of Justice of the European Union and the Swiss-U.S. Privacy Shield Framework was declared as inadequate by the Swiss Federal Data Protection and Information Commissioner. The decision by the Court of Justice and the announcement by the Swiss Commissioner both raised questions about whether one of the primary alternatives to the Privacy Shield frameworks, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Authorities in the U.K. may similarly invalidate use of the EU-U.S. Privacy Shield and raise questions on the viability of the Standard Contractual Clauses. In November 2020, EU regulators proposed a new set of Standard Contractual Clauses, which impose additional obligations and requirements with respect to the transfer of EU personal data to other jurisdictions, which may increase the legal risks and liabilities under the GDPR and local EU laws associated with cross-border data transfers, and result in material increased compliance and operational costs. If we are unable to implement a valid solution for personal information transfers to the United States and other countries, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe, and we may be required to increase our data processing capabilities in Europe at significant expense. Inability to import personal information from Europe to the United States or other countries may decrease demand for our products and services as our customers that are subject to the GDPR may seek alternatives that do not involve personal information transfers out of Europe. At present, there are few, if any, viable alternatives to the Privacy Shield and the Standard Contractual Clauses.

In addition, it is unclear whether the transfer of personal information from the EU to the U.K. will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the U.K. and the EU, transfers of personal information from the EEA to the U.K. are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an adequacy finding with respect to the U.K. before the end of that period, the U.K. will be considered a "third country" under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers lawful under the GDPR. Additionally, although U.K. privacy, data protection and data security law is designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

Other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the GDPR.

Regulation of privacy, data protection and data security has also become more stringent in the United States. For example, the CCPA, which took effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. 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 state privacy, data protection and data security legislation in the U.S., which could increase our potential liability and adversely affect our business. The CCPA will be expanded substantially on January 1, 2023, when the CPRA becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law.

Compliance with U.S. and foreign privacy, data protection, and data security laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign privacy, data protection, and data security laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data protection, and data security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

If our security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our services, compromise sensitive information related to our business, harm our reputation, trigger our breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business.

In the ordinary course of our business, we may collect, process, and store proprietary, confidential, and sensitive information, including personal information (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and availability of such information. We face several risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third-party service providers who handle elements of our operations.

We, our partners, our CROs, our CMOs, and other business vendors on which we rely depend on information technology and telecommunication systems for significant elements of our operations, including, for example, systems handling human resources, financial reporting and controls, regulatory compliance and other infrastructure operations. Notwithstanding the implementation of security measures, given the size and complexity of our information technology systems and those of our third-party vendors and other contractors and consultants, and the increasing amounts of proprietary, confidential and sensitive information that they maintain, such information technology systems are potentially vulnerable to breakdown, service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third-party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure, or that of our third-party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through accidental actions or omissions by trusted insiders, cyber-attacks or cyber intrusions, including by computer hackers, viruses, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, the increased usage of computers operated on home networks due to the shelter-in-place or similar restrictions related to the COVID-19 pandemic may make our systems more susceptible to security breaches. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions to our operations, including preventing us from conducting tests or research and development activities and preventing us from managing the administrative aspects of our business. For example, the loss of clinical study data from completed, ongoing or planned clinical studies 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 results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

We may not be able to anticipate all types of security threats, and we may not be able to implement preventative measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, hostile foreign governments or agencies, or cybersecurity researchers. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our products and services could be delayed.

The costs related to significant security breaches or disruptions could be material and could exceed the limits of the cybersecurity insurance we maintain, if any, against such risks. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

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

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen.

Any such access, breach, or other loss of information could result in legal claims or proceedings, liability under domestic or foreign privacy, data protection and data security laws such as HIPAA and HITECH, and penalties. Notice of certain security breaches must be made to affected individuals, the Secretary of HHS, and for extensive breaches, notice may need to be made to the media or state attorneys general. Such notice could harm our reputation and our ability to compete. Although we have implemented security measures, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process and prepare company financial information, and manage the administrative aspects of our business.

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state afford greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. Similarly, the CCPA allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our products, decrease demand for our products, reduce our revenues and/or subject us to additional liabilities.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act repealed or modified in future legislation. For example, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any other newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense. However, given our valuation allowance position, the Tax Act is not expected to have a significant impact on our effective tax rate, cash tax expenses or net deferred tax assets.

Our ability to use net operating loss carryforwards and certain tax assets to offset future taxable income or taxes may be subject to certain limitations.

Our ability to use our federal and state net operating losses (NOLs), to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

As of December 31, 2020, we reported U.S. federal and state NOLs of approximately $811.7 million and $988.1 million, respectively. Our federal NOLs generated in tax years beginning prior to January 1, 2018 aggregating to $65.3 million will continue to be governed by the NOL tax rules as they existed prior to the adoption of the Tax Act, which means that generally they will expire 20 years after they were generated if not used prior thereto. Many states have similar laws, and our state NOLs will begin to expire in 2030. Accordingly, these federal and state NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, as modified by the CARES Act, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the utilization of such federal NOLs arising in taxable years beginning after December 31, 2020 is limited to 80% of current year taxable income. The CARES Act temporarily suspends this 80% taxable income limitation, allowing an NOL carryforward to fully offset taxable income in tax years beginning before 2021. Not all states conform to the Tax Act or CARES Act and other states have varying conformity to the Tax Act or CARES Act.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an "ownership change". Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year testing period. Similar rules may apply under state tax laws. We completed a Section 382 study of transactions in our stock through December 31, 2020 and concluded that we have experienced ownership changes since inception that we believe under Section 382 of the Code will result in limitations on our ability to use certain pre-change NOLs and credits. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and, in the case of NOLs generated in tax years beginning on or before December 31, 2017, may expire unused. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs or other tax attributes is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state NOLs and certain tax attributes in tax years beginning after 2019 and before 2023.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Two of our corporate locations are located in California, an area prone to earthquakes and fires. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, including, for example, the ongoing COVID-19 pandemic.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located in South San Francisco, California and consists of approximately 13,670 square feet of office space under a lease agreement that expires in May 2022. We also lease approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California under a lease for which the initial 15-year term commenced in February 2018. Additionally, in November 2018, we entered into a lease agreement for approximately 51,160 square feet of office space in Thousand Oaks, California that expires in February 2026.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock has been listed on The Nasdaq Global Select Market under the symbol "ATRA" since October 16, 2014. Prior to that time, there was no public market for our common stock.

On February 18, 2021, there were 6 stockholders of record of our common stock. We are unable to estimate the total number of stockholders represented by these record holders, as many of our shares are held by brokers and other institutions on behalf of our stockholders.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any further determination to pay dividends on our capital stock will be at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

Securities Authorized for Issuance under Equity Compensation Plans

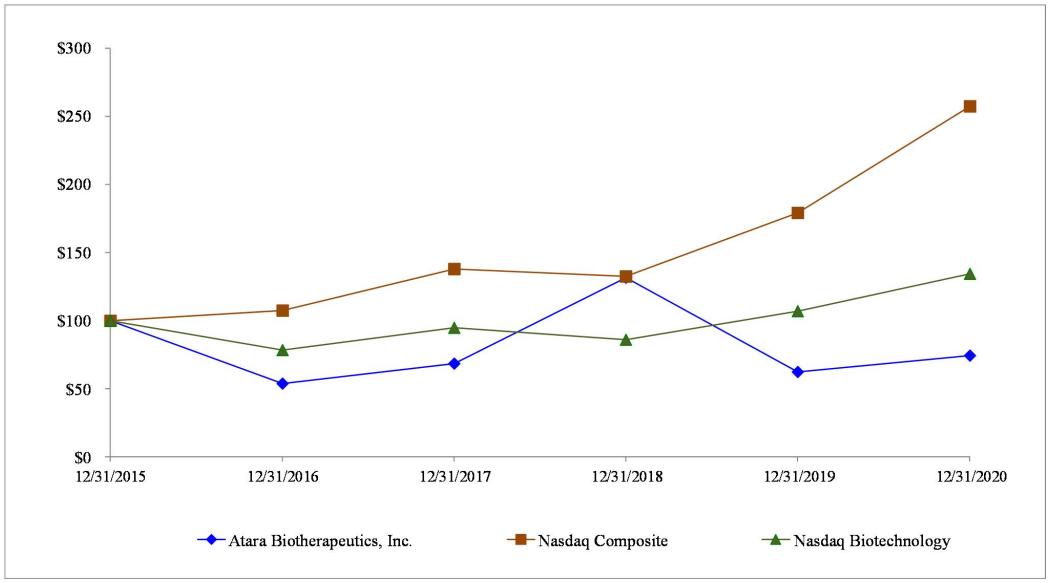
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Stock Performance Graph

The following graph compares the cumulative total return on an indexed basis of a $100 investment, made at the beginning of the five-year period ended December 31, 2020, in the Company's common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index.

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act or incorporated by reference into any filing of Atara Biotherapeutics, Inc. under the Securities Act or the Exchange Act, except to the extent we specifically incorporate it by reference into such filing. The past performance of our common stock is not an indication of future performance.

COMPARISON OF FIVE-YEAR CUMULATIVE TOTAL RETURN



As of December 31,	Atara Biotherapeutics, Inc.	Nasdaq Composite	Nasdaq Biotechnology
2015	$ 100.00	$ 100.00	$ 100.00
2016	53.77	107.50	78.32
2017	68.53	137.86	94.81
2018	131.54	132.51	85.97
2019	62.36	179.19	106.95
2020	74.33	257.38	134.42

Item 6. Selected Financial Data

The following selected consolidated financial data of the Company for each of the periods indicated are derived from the Company's audited consolidated financial statements. The consolidated financial statements of the Company as of December 31, 2020 and 2019 and for the years ended December 31, 2020, 2019 and 2018, and the related reports of the independent registered public accounting firm are included elsewhere in this Annual Report on Form 10-K. The data presented below should be read in conjunction with the Company's financial statements, the notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

Consolidated Statements of Operations and Comprehensive Loss Data:	**Year ended December 31,**				
	2020	**2019**	**2018**	**2017**	**2016**
	(In thousands, except per share amounts)				
Operating expenses:					
Research and development	$ 244,650	$ 216,097	$ 167,457	$ 81,206	$ 56,514
General and administrative	64,402	79,584	69,654	40,326	24,728
Total operating expenses	309,052	295,681	237,111	121,532	81,242
Loss from operations	(309,052)	(295,681)	(237,111)	(121,532)	(81,242)
Interest and other income, net	2,447	4,717	6,368	2,027	2,203
Loss before provision for income taxes	(306,605)	(290,964)	(230,743)	(119,505)	(79,039)
Provision for (benefit from) income taxes	15	12	(44)	(14)	10
Net loss	$ (306,620)	$ (290,976)	$ (230,699)	$ (119,491)	$ (79,049)
Other comprehensive gain (loss):					
Unrealized gain (loss) on available-for-sale securities	76	560	(189)	32	335
Comprehensive loss	$ (306,544)	$ (290,416)	$ (230,888)	$ (119,459)	$ (78,714)
Basic and diluted net loss per common share	$ (4.15)	$ (5.67)	$ (5.27)	$ (4.00)	$ (2.75)

Consolidated Balance Sheet Data:	**As of December 31,**				
	2020	**2019**	**2018**	**2017**	**2016**
	(In thousands)				
Cash, cash equivalents and short-term investments	$ 500,659	$ 259,109	$ 309,631	$ 166,096	$ 255,682
Working capital	$ 440,372	$ 236,249	$ 281,510	$ 144,544	$ 250,878
Total assets	$ 588,120	$ 342,942	$ 391,839	$ 217,779	$ 263,914
Long-term liabilities	$ 42,880	$ 15,418	$ 13,003	$ 12,269	$ 503
Total stockholders' equity	$ 462,339	$ 290,781	$ 338,857	$ 177,864	$ 253,736

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 audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Atara Biotherapeutics is a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with serious diseases, including solid tumors, hematologic cancers and autoimmune disease. With our lead program in Phase 3 clinical development, we are the most advanced allogeneic T-cell immunotherapy company and intend to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-driven diseases or other serious diseases through incorporation of engineered CARs or TCRs. Atara is applying this one platform to create a robust pipeline. Our strategic priorities are:

- ***Tab-cel®***: Atara's most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), currently in Phase 3 development for patients with EBV+ PTLD who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-driven diseases;
- ***ATA188***: T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis;
- ***CAR T Programs***:
    - ***ATA2271***: Autologous CAR T immunotherapy targeting solid tumors expressing the tumor antigen mesothelin, which is partnered with Bayer;
    - ***ATA3271***: Allogeneic CAR T therapy targeting mesothelin, which is partnered with Bayer; and
    - ***ATA3219***: Allogeneic CAR T targeting CD19 and being developed as a potential best-in-class product, based on a next generation 1XX co-stimulatory domain and the innate advantages of EBV T cells as the foundation for an allogeneic CAR T platform.

Our T-cell immunotherapy platform includes the capability to progress both allogeneic and autologous programs and is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. For our allogeneic programs, we select the appropriate set of cells for use based on a patient's unique immune profile.

In December 2020, we entered into the Bayer License Agreement, pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271. Under the terms of the Bayer License Agreement, we will be responsible at our cost for all mutually agreed preclinical and clinical activities for ATA2271 through the first in human Phase 1 clinical study in collaboration with MSK, following which Bayer will be responsible for the further development of ATA2271 at its cost. Bayer will be responsible for the development of ATA3271, except for certain mutually agreed preclinical, translational, manufacturing and supply chain activities to be performed by us relating to ATA3271, in each case at Bayer's cost. Bayer will also be solely responsible for commercializing the Licensed Products at its cost.

We have also entered into research collaborations with leading academic institutions such as MSK, QIMR Berghofer and Moffitt pursuant to which we acquired rights to novel and proprietary technologies and programs.

Our manufacturing facility in Thousand Oaks, California has the flexibility to manufacture multiple T-cell and CAR T immunotherapies while integrating research and process science functions to enable increased collaboration for rapid product development. We are currently in the process of completing our facility's commercial production qualification activities for tab-cel® while building inventory according to our commercial product supply strategy.

In addition to our manufacturing facility, we also work with Cognate pursuant to the Manufacturing Agreement that we entered into in December 2019. Pursuant to the Manufacturing Agreement, Cognate provides manufacturing services for certain of our product candidates. The initial term of the Manufacturing Agreement runs until December 31, 2021 and is renewable with Cognate's approval for an additional one-year period.

We have a limited operating history. Since our inception in 2012, we have devoted substantially all of our resources to identify, acquire and develop our product candidates, including conducting preclinical and clinical studies, acquiring or manufacturing materials for clinical studies, constructing our manufacturing facility and providing general and administrative support for these operations.

Our net losses were $306.6 million, $291.0 million and $230.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $1.1 billion. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. As of December 31, 2020, our cash, cash equivalents and short-term investments totaled $500.7 million, which we intend to use to fund our operations.

Financial Overview

Revenues

We have never generated revenues from the sale of products and have incurred losses since inception. We do not expect to receive any revenue from product sales unless and until we obtain regulatory approval for and commercialize one of our current or future product candidates. Further, we have not generated any revenue to date from the Bayer License Agreement.

We expect that any revenue we generate from our Bayer License Agreement and any future collaboration and research and license partners will fluctuate from year to year as a result of the timing and number of milestones and other payments.

Research and Development Expenses

The largest component of our total operating expenses since inception has been our investment in research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with contract research organizations and investigative sites that conduct preclinical and clinical studies; the costs of acquiring and manufacturing clinical study materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

We plan to continue investment in the development of our product candidates. Our current planned research and development activities include the following:

- continuing to initiate sites and enroll patients in our Phase 3 clinical study of tab-cel® for the treatment of patients with EBV+ PTLD after HCT and SOT who have failed rituximab;
- process development, testing and manufacturing of drug supply to support clinical studies and IND-enabling studies;
- continuing development of ATA188 in progressive MS;
- continuing to develop product candidates based on our next-generation CAR T programs;
- continuing to develop our product candidates in additional indications, including tab-cel® for EBV+ cancers;
- continuing to develop other preclinical product candidates; and
- leveraging our relationships and experience to in-license or acquire additional product candidates or technologies.

In addition, we believe it is important to invest in the development of new product candidates to continue to build the value of our product candidate pipeline and our business. We plan to continue to advance our most promising early product candidates into preclinical development with the objective to advance these early-stage programs to human clinical studies over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs, and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

- the availability of qualified drug supply for use in our ongoing Phase 3 or other clinical studies;
- the scope, rate of progress, and expenses of our ongoing clinical studies, potential additional clinical studies and other research and development activities;
- the potential review or reanalysis of our clinical study results;
- future clinical study results;
- uncertainties in clinical study enrollment rates or discontinuation rates of patients, including any potential impact of the COVID-19 pandemic;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- changing medical practice patterns related to the indications we are investigating;
- significant and changing government regulation;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic; and
- the timing and receipt of any regulatory approvals, as well as potential post-market requirements.

The process of conducting the necessary clinical research to obtain approval from the FDA and other regulators is costly and time consuming and the successful development of our product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this report titled "1A. Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation and benefits for legal, human resources, finance, commercial and other general and administrative employees, including stock-based compensation; professional services costs, including legal, patent, human resources, audit and accounting services; other outside services and consulting costs, including those related to pre-commercial activities; and information technology and facilities costs.

Interest and Other Income, net

Interest and other income, net consists primarily of interest earned on our cash, cash equivalents and short-term investments.

Income Taxes

Our provision for (benefit from) income taxes consists primarily of income taxes in U.S. state and foreign jurisdictions. Our effective tax rate was 0% for the years ended December 31, 2020, 2019, and 2018.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on ourconsolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant judgments and estimates are detailed below, and our significant accounting policies are more fully described in Note 2 of the accompanying consolidated financial statements.

Revenue Recognition

Revenue from research activities under our research, development, and license agreements is recognized when our customer obtains control of the promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Revenue generated from our research, development, and license agreements is not subject to repayment and typically includes upfront fees, development, regulatory and commercial milestone payments and royalties on the licensee's future product sales.

Our research, development, and license agreements may include the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. We assess whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether licenses to our intellectual property are distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price (SSP) of each distinct performance obligation. Due to the early stage of our licensed technology, the license of such technology is typically combined with the research and development services and committee participation as one combined performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development activities cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using a cost-based input method. We utilize judgment to assess the pattern of delivery of the performance obligation. A cost-based input method of revenue recognition requires management to make estimates of costs to complete our performance obligations. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligations will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in the assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

At the inception of each agreement that includes development, regulatory or commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is allocated to each performance obligation in the agreement based on relative SSP. We typically determine SSPs using an adjusted market assessment approach model. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of each such milestone and any related constraint, and if necessary, adjust our estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Certain judgments affect the application of our revenue recognition policy. For example, we record short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months, and long-term deferred revenue consists of amounts that we do not expect will be recognized in the next 12 months. This estimate is based on the our current operating plan and, if our operating plan should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate and accrue expenses, the largest of which is related to research and development expenses, including those related to clinical studies and drug manufacturing. This process involves reviewing contracts and purchase orders, identifying and evaluating the services that have been performed on our behalf, and estimating the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs.

Costs for preclinical studies, clinical studies and manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

For the years ended December 31,2020 and 2019, there were no material changes from our estimates of accrued research and development expenses.We do not believe there is a reasonable likelihood that there will be a material change in the future estimates of accrued research and development expenses. However, if actual results are not consistent with our estimates, we may be exposed to changes in accrued research and development expenses that could be material or the accrued research and development expenses reported in our financial statements may not be representative of the actual economic cost of accrued research and development.

Stock-based Compensation

We have stock-based compensation programs, which include restricted stock units (RSUs); stock options and an employee stock purchase plan. See Note 2 – "Summary of Significant Accounting Policies" and Note 10 – "Stockholders' Equity" in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for a complete discussion of our stock-based compensation programs. We account for stock-based compensation expense, including the expense for grants of RSUs and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant. The fair value of our RSUs is the fair value of the underlying stock at the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model.

Assumptions for the Black-Scholes valuation model used for employee stock awards include:

- Expected term – We derived the expected term for employee stock awards using the "simplified" method (the expected term is determined as the average of the time-to-vesting and the contractual life of the options), as we have limited historical information to develop expectations about future exercise patterns and post vesting employment termination behavior. Expected term for non-employee awards is based on the remaining contractual term of an option on each measurement date.
- Expected volatility – Expected volatility is estimated using comparable public companies' volatility for similar terms.
- Expected dividend rate – We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore, we have assumed an expected dividend yield of 0%.
- Risk-free interest rate – The risk-free interest rate is based on the yields of U.S. Treasury securities with expected terms similar to that of the associated award.
- The fair value of our common stock is based on observable market prices.

For awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and begin to recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. We do not believe there is a reasonable likelihood that there will be a material change in the future estimates or assumptions we use to determine stock-based compensation expense. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to changes in stock-based compensation expense that could be material or the stock-based compensation expense reported in our financial statements may not be representative of the actual economic cost of the stock-based compensation.

Accounting for Income Taxes

See Note 11 – "Income Taxes" in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for a complete discussion of the components of Atara's income tax expense, as well as the temporary differences that exist as of December 31, 2020.

Our consolidated effective income tax rate is influenced by tax planning opportunities available to us in the various jurisdictions in which we conduct business. Significant judgment is required in evaluating our tax positions, including those that may be uncertain. Atara is also required to exercise judgment with respect to the realization of our net deferred tax assets. Management evaluates all positive and negative evidence and exercises judgment regarding past and future events to determine if it is more likely than not that all or some portion of the deferred tax assets may not be realized. If appropriate, a valuation allowance is recorded against deferred tax assets to offset future tax benefits that may not be realized.

We do not believe that there is a reasonable likelihood that there will be a material change in our liability for uncertain income tax positions or our effective income tax rate. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to losses that could be material. Atara recorded a valuation allowance of approximately $287.3 million as of December 31, 2020 related primarily to net operating losses, capitalized expenses and stock-based compensation.

Results of Operations

Comparison of the Years Ended December 31, 2020, 2019 and 2018

Research and development expenses

Research and development expenses consisted of the following costs, by program, in the periods presented:

	Year ended December 31,			Increase (Decrease)	
	2020	2019	2018	2020 compared to 2019	2019 compared to 2018
			(in thousands)		
Tab-cel® expenses	$ 61,196	$ 49,179	$ 50,822	$ 12,017	$ (1,643)
ATA188, CAR T and other program expenses	25,124	34,869	30,155	(9,745)	4,714
Employee and overhead expenses	158,330	132,049	86,480	26,281	45,569
Total research and development expenses	$ 244,650	$ 216,097	$ 167,457	$ 28,553	$ 48,640

Tab-cel® expenses were $61.2 million in 2020 as compared to $49.2 million in 2019 and $50.8 million in 2018.Tab-cel® expenses increased in 2020 due to clinical trials and process performance qualification activities at our manufacturing facility, as well as increased activity to support our tab-cel® BLA filing. The slight decrease in 2019 as compared to 2018 was primarily due to higher clinical trial and manufacturing costs in 2018 related to the ramp up of the MATCH and ALLELE Phase 3 clinical studies for patients with EBV+ PTLD.

ATA188, CAR T and other program expenses were $25.1 million in 2020 as compared to $34.9 million in 2019 and $30.2 million in 2018. The decrease in 2020 was primarily due to lower clinical study, manufacturing and other outside services costs for programs that are no longer in active development. The increase in 2019 was primarily related to research and manufacturing process development costs related to our CAR T programs; increased clinical study, manufacturing and other outside service costs related to the Phase 1 clinical study of ATA188 for patients with PMS; and other programs.

Employee and overhead expenses were $158.3 million in 2020 as compared to $132.0 million in 2019 and $86.5 million in 2018. The increases were primarily due to higher compensation-related costs from increased headcount and higher facility-related costs in support of our continuing expansion of research and development activities. Payroll and related costs increased by $21.2 million in 2020 as compared to 2019 and by $29.6 million in 2019 as compared to 2018. Facility-related costs increased by $5.1 million in 2020 as compared to 2019 and by $10.4 million in 2019 as compared to 2018. Outside service costs remained consistent in 2020 as compared to 2019 and increased by $5.6 million in 2019 as compared to 2018.

Total research and development expenses for 2020 were not significantly impacted as a result of the COVID-19 pandemic.

General and administrative expenses

General and administrative expenses for the periods indicated were as follows:

	Year ended December 31,			(Decrease) Increase	
	2020	2019	2018	2020 compared to 2019	2019 compared to 2018
			(in thousands)		
General and administrative expenses	$ 64,402	$ 79,584	$ 69,654	$ (15,182)	$ 9,930

General and administrative expenses were $64.4 million in 2020 as compared to $79.6 million in 2019 and $69.7 million in 2018. The decrease of $15.2 million in 2020 was primarily due to decreases of $10.1 million in outside services costs and $5.1 million in non-cash stock-based compensation expenses. The increase of $9.9 million in 2019 was primarily due to increases in compensation-related costs driven by increased headcount. Total general and administrative expenses for 2020 were not significantly impacted as a result of the COVID-19 pandemic.

Quarterly Results of Operations Data (unaudited)

The following table sets forth our unaudited consolidated statement of operations data for each of the quarterly periods in the years ended December 31, 2020 and 2019. The unaudited quarterly statement of operations data set forth below have been prepared on a basis consistent with our audited annual consolidated financial statements in this Annual Report on Form 10-K and include, in our opinion, all normal recurring adjustments necessary for a fair statement of the financial information contained in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The following quarterly financial data should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K.

	Three months ended			
	March 31	June 30	September 30	December 31
2020	(In thousands, except per share amounts)			
Operating expenses:				
Research and development	$ 57,659	$ 61,560	$ 59,877	$ 65,554
General and administrative	17,038	16,392	14,829	16,143
Total operating expenses	74,697	77,952	74,706	81,697
Loss from operations	(74,697)	(77,952)	(74,706)	(81,697)
Interest and other income, net	1,188	497	364	398
Loss before provision for income taxes	(73,509)	(77,455)	(74,342)	(81,299)
Provision for income taxes	—	1	6	8
Net loss	(73,509)	(77,456)	(74,348)	(81,307)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on available-for-sale securities	(16)	606	(283)	(231)
Comprehensive loss	$ (73,525)	$ (76,850)	$ (74,631)	$ (81,538)
Basic and diluted net loss per common share	$ (1.20)	$ (1.14)	$ (0.92)	$ (0.95)

	Three months ended			
	March 31	June 30	September 30	December 31
2019	(In thousands, except per share amounts)			
Operating expenses:				
Research and development	$ 48,668	$ 52,251	$ 53,538	$ 61,640
General and administrative	19,223	23,284	19,018	18,059
Total operating expenses	67,891	75,535	72,556	79,699
Loss from operations	(67,891)	(75,535)	(72,556)	(79,699)
Interest and other income, net	1,634	1,207	661	1,215
Loss before provision for income taxes	(66,257)	(74,328)	(71,895)	(78,484)
Provision for income taxes	—	—	—	12
Net loss	(66,257)	(74,328)	(71,895)	(78,496)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	378	135	60	(13)
Comprehensive loss	$ (65,879)	$ (74,193)	$ (71,835)	$ (78,509)
Basic and diluted net loss per common share	$ (1.44)	$ (1.60)	$ (1.31)	$ (1.36)

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common and preferred stock, issuance of pre-funded warrants to purchase common stock and upfront fees from the Bayer License Agreement.

In December 2020, we completed an underwritten public offering of 5,102,041 shares of common stock at a public offering price of $24.50 per share and pre-funded warrants to purchase 2,040,816 shares of common stock at a public offering price of $24.4999 per warrant. We received net proceeds of approximately $164.3 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

In the second quarter of 2020, we completed an underwritten public offering of 14,958,039 shares, inclusive of the exercise of the full option granted to the underwriters, of common stock at a public offering price of $11.32 per share and pre-funded warrants to purchase 2,866,961 shares of common stock at a public offering price of $11.3199 per warrant. We received net proceeds of approximately $189.3 million after deducting underwriting discounts and commissions and offering expenses payable by us.

In July 2019, we completed an underwritten public offering of 6,871,727 shares of common stock at a public offering price of $15.28 per share and pre-funded warrants to purchase 2,945,026 shares of common stock at a public offering price of $15.2799 per warrant. We received aggregate net proceeds of approximately $140.7 million after deducting underwriting discounts and commissions and offering expenses payable by us.

In February 2019, we entered into a sales agreement (the 2019 ATM Facility) with Cowen and Company, LLC (Cowen), which provided for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The issuance and sale of these shares by us pursuant to the 2019 ATM Facility were deemed "at the market" offerings defined in Rule 415 under the Securities Act of 1933, as amended (the Securities Act), and were registered under the Securities Act. We paid a commission of up to 3.0% of gross sales proceeds of the common stock sold under the 2019 ATM Facility.

In February 2020, we entered into a new sales agreement (the 2020 ATM Facility) with Cowen, which provides for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The 2020 ATM Facility is separate from and does not replace the 2019 ATM Facility in any way. The issuance and sale of these shares by us pursuant to the 2020 ATM Facility are deemed "at the market" offerings and are registered under the Securities Act. We pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2020 ATM Facility.

During the year ended December 31, 2020, we sold an aggregate of 4,785,514 shares of common stock under the ATM facilities, at an average price of $14.60 per share for net proceeds of $68.0 million, after deducting commissions and other offering expenses payable by us. On January 3, 2020, we received net proceeds of approximately $1.2 million from sales of shares of our common stock under the 2019 ATM Facility that occurred during December 2019.

As of December 31, 2020, we have fully utilized the 2019 ATM Facility and $79.7 million of common stock remained available to be sold under the 2020 ATM Facility, subject to certain conditions as specified in the agreement.

We have incurred losses and negative cash flows from operations in each year since inception. We do not expect to receive any revenues from the sale of products unless and until we obtain regulatory approval for and commercialize any of our product candidates. As such, we anticipate that we will continue to incur losses in the foreseeable future. Additionally, as a result of the COVID-19 pandemic, we have experienced, and may experience in the future, disruptions that could severely impact our business, preclinical studies and clinical trials. We expect that our operating expenses will continue to increase. As a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings including by utilizing the 2020 ATM Facility, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing. However, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a consequence, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. We may face similar difficulties in obtaining funding through debt financing or other arrangements. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses or other rights on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash, cash equivalents and short-term investments are held in bank and custodial accounts and consist of money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities.

Our cash, cash equivalents and short-term investments balances as of the dates indicated were as follows:

	December 31, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 200,404	$ 74,317
Short-term investments	300,255	184,792
Total cash, cash equivalents and short-term investments	$ 500,659	$ 259,109

Cash Flows

The following table details the primary sources and uses of cash for each of the periods set forth below:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (180,759)	$ (235,626)	$ (179,772)
Investing activities	(120,728)	60,459	(196,289)
Financing activities	427,574	188,786	357,536
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 126,087	$ 13,619	$ (18,525)

Operating activities

Net cash used in operating activities was $180.8 million in 2020 as compared to $235.6 million in 2019. The decrease of $54.9 million was primarily due to $52.9 million received as a result of the Bayer License Agreement, a $14.9 million increase in other net operating liabilities and a $2.2 million increase in the amortization of investment premiums, partially offset by a $15.6 million increase in net loss.

Net cash used in operating activities was $235.6 million in 2019 as compared to $179.8 million in 2018. The increase of $55.8 million was primarily due to a $60.3 million increase in net loss and a $19.2 million increase in net operating assets, partially offset by a $17.9 million increase in stock-based compensation, a $3.3 million increase in depreciation and amortization expense, and a $1.0 million increase in loss on disposals of property and equipment.

Investing activities

Net cash used in investing activities in 2020 consisted primarily of $425.9 million used to purchase available-for-sale securities and $4.5 million in purchases of property and equipment, partially offset by $309.7 million received from maturities and sales of available-for-sale securities.

Net cash provided by investing activities in 2019 consisted primarily of $336.3 million received from maturities and sales of available-for-sale securities, partially offset by $270.2 million used to purchase available-for-sale securities and $5.7 million in purchases property and equipment.

Net cash used in investing activities in 2018 consisted primarily of $466.5 million used to purchase available-for-sale securities and $35.9 million used to purchase property and equipment, partially offset by $306.1 million received from maturities and sales of available-for-sale securities.

Financing activities

Net cash provided by financing activities in 2020 consisted primarily of $353.8 million of aggregate net proceeds received from the two underwritten public offerings of common stock and pre-funded warrants, $69.2 million of net proceeds from ATM facilities

and $6.7 million of net proceeds from employee stock award transactions, partially offset by $1.5 million of taxes paid related to the net share settlement of RSUs.

Net cash provided by financing activities in 2019 consisted primarily of $140.9 million of net proceeds received from an underwritten public offering of common stock and pre-funded warrants, $47.7 million of net proceeds from ATM facilities and $7.4 million of net proceeds from employee stock award transactions, partially offset by $6.7 million of taxes paid related to the net share settlement of RSUs.

Net cash provided by financing activities in 2018 consisted of $293.3 million of aggregate net proceeds from the underwritten public offerings in January and March 2018, $47.6 million of net proceeds from ATM facilities and $24.7 million of net proceeds from employee stock award transactions, partially offset by $7.5 million of taxes paid related to the net share settlement of restricted stock and $0.5 million of principal payments on capital lease obligations.

Operating Capital Requirements and Plan of Operations

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the accumulated losses to increase as we continue the development of and seek regulatory approvals for our product candidates and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need to raise substantial additional funding in connection with our continuing and expected expansion of our operations.

We expect that our existing cash, cash equivalents and short-term investments as of December 31, 2020, together with projected revenue from U.S. tab-cel® sales, if approved, will be sufficient to fund our operations into 2023, including expenses related to the BLA filing and potential commercial launch of tab-cel® in the U.S. In order to complete the process of obtaining regulatory approval for any of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, costs and results of our ongoing and planned clinical and preclinical studies for our product candidates, including any potential impact of the COVID-19 pandemic;
- our success in establishing and scaling commercial manufacturing capabilities;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of regulatory approval, costs associated with the commercialization of our product candidates and the amount of revenues received from commercial sales of our product candidates;
- the timing of proceeds from the Bayer License Agreement, as well as the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;
- the extent to which we in-license or acquire other products and technologies; and
- the timing of capital expenditures, including the qualification of our manufacturing facility.

Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We expect to continue to seek access to the equity and debt capital markets to support our development efforts and operations. To the

extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses or other rights on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty, political change and other factors, including the ongoing COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we will be forced to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates.

Contractual Obligations and Commitments

We lease our corporate headquarters in South San Francisco, California under a non-cancellable lease agreement for approximately 13,670 square feet of office space. In October 2020, we entered into an amendment of this lease to extend the lease term by one year and an option to extend the lease for an additional five years. The amended lease expires in May 2022.

In February 2017, we entered into a lease agreement for approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California. The initial 15-year term of this lease commenced in February 2018, and the contractual obligations during the initial term are $16.4 million in aggregate. We have the option to extend this lease for two additional periods of ten and nine years, respectively, after the initial term. In connection with this lease, we were required to issue a letter of credit in the amount of $1.2 million to the landlord, which is recorded as long-term restricted cash in our consolidated balance sheet.

In November 2018, we entered into a lease agreement for approximately 51,160 square feet of office space in Thousand Oaks, California. The initial term of this lease expires in February 2026. The contractual obligations during the initial term are $8.5 million in aggregate. We have the option to extend the lease for an additional period of five years after the initial term.

In May 2019, we entered into a new lease agreement for approximately 8,800 square feet of office and lab space in Aurora, Colorado. The term of this lease expires in April 2024. The contractual obligations during the lease term are $1.1 million in aggregate.

The following table summarizes our contractual obligations as of December 31, 2020:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations	$ 23,188	$ 3,177	$ 5,531	$ 5,180	$ 9,300
Finance lease obligations	441	282	159	—	—
Purchase obligations (1)	12,720	12,720	—	—	—
Total contractual obligations	$ 36,349	$ 16,179	$ 5,690	$ 5,180	$ 9,300

(1) We enter into contracts in the normal course of business with clinical research organizations for clinical studies, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies and supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, with the exception of one of our contract manufacturing agreements which we may terminate for convenience upon six months' written notice. Payments in the table above represent our estimate of contractual minimum purchase obligations. Arrangements are considered purchase obligations if a contract specifies all significant terms, including fixed or minimum quantities to be purchased, a pricing structure and approximate timing of the transaction. Payments in the table above do not include any termination penalties or fees.

The above amounts exclude potential milestone and royalty payments related to our license and collaboration agreements, as the achievement of these milestones is currently not fixed and determinable.

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 SEC.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate and Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2020, we had total cash, cash equivalents and short-term investments of $500.7 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. We currently do not hedge our interest rate risk exposure.Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate change in interest rates of 10 basis points would not result in a significant change in the fair market value of our portfolio.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and short-term and long-term investments in a variety of securities, including money market funds, U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities. These securities are all classified as available-for-sale and consequently are recorded on the balance sheet at fair value, with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). Our holdings of the securities of any one issuer, except for obligations of the U.S. Treasury, U.S. Treasury-guaranteed securities or money market funds, do not exceed 5% of our portfolio.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of Atara Biotherapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Atara Biotherapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2021 expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases in 2019 due to adoption of Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, using the optional transition method.

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 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. 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue and Deferred Revenue – Accounting for Research, Development and License Agreement – Refer to Note 7 to the Financial Statements

Critical Audit Matter Description

The Company entered into a research, development, and license agreement with Bayer AG ("Bayer") (the "Bayer License Agreement") in December 2020 to develop mesothelin-directed CAR T-cell therapies for the treatment of solid tumors, pursuant to which the Company granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by the Company and its affiliates covering or related to ATA2271 and ATA3271. Under the terms of the Bayer License Agreement, the Company will be responsible at its cost for all mutually agreed preclinical and clinical activities for ATA2271 through the first in human Phase 1 clinical study. The Company promised a development and commercialization license, the performance of early-stage research and development services, including technology transfer services, joint steering committee participation, and chemistry, manufacturing and control services. In December 2020, the Company received an upfront cash payment of $45.0 million from Bayer for the exclusive license grant, net of applicable withholding taxes, received an additional $15.0 million upfront reimbursement payment from Bayer for certain research and process development activities, and invoiced Bayer $1.3 million for additional, specified translational activities.

The Company determined the Bayer License Agreement is within the scope of Accounting Standards Codification Topic 606 (ASU No. 2014-09),*Revenue from Contracts with Customers*, and all subsequent amendments (collectively, "ASC 606") and concluded that the promises in the Bayer License Agreement represent transactions with a customer. In applying ASC 606, the Company has determined the promises in the agreement are highly interdependent upon one another and combined its promises into a single performance obligation. The Company will utilize a cost-based input method to measure its progress toward completion of its performance obligation to calculate the corresponding amount of revenue to recognize each period. In applying the cost-based input method, management uses significant judgment in evaluating assumptions related to its cost estimates. As of December 31, 2020, the Company did not recognize any revenue under the Bayer License Agreement and deferred revenue amounted to $61.3 million, of which $33.5 million is included in current liabilities and $27.8 million is included in long-term liabilities.

We identified accounting for the Bayer License Agreement and the estimated deferred revenue to be recognized as revenue over time as a critical audit matter. Given the judgments necessary to determine the accounting literature to apply to a research, development and license agreement, the estimated future costs to be used in applying the cost-based input method to measure progress toward the completion of the performance obligation and the estimated contractual term over which the performance obligation would be completed, auditing such judgments and estimates required extensive audit effort due to the complexity of the Bayer License Agreement and the high degree of auditor judgment applied when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to determining the accounting literature to apply to a research, development and license agreement and management's estimates of costs used in the cost-based input method for measuring progress included the following, among others:

- We tested the operating effectiveness of controls over contract revenue, including those over determining the accounting literature to apply to an agreement, the estimates of total costs, and the estimated measure of progress when revenue is recognized over time.
- Evaluated management's determination that the Bayer License Agreement is within the scope of ASC 606.
- Tested management's identification of the single performance obligation by evaluating whether the promises to provide a development and commercialization license, the performance of early-stage research and development services, including technology transfer services, joint steering committee participation, and chemistry, manufacturing and control services were highly interdependent and interrelated.
- Evaluated management's determination of the contractual term and the appropriateness of management's method to measure its progress over that term.
- Evaluated the assumptions used in the estimates of total costs and the estimated measure of progress for recognizing revenues over time revenue by:
    - Evaluating management's ability to achieve the estimates of costs by performing corroborating inquiries with the Company's project and business development managers, and comparing the assumptions used in the estimates to management's work plans and cost estimates.
    - Tested the mathematical accuracy of management's current and long-term deferred revenue balances based on the estimated revenue to be recognized over time.

Accrued Research and Development Expenses & Prepaid Research and Development Expenses (Clinical Trial Accrued and Prepaid Expenses) - Refer to Note 2 to the Financial Statements

Critical Audit Matter Description

The Company recognizes costs it incurs for preclinical studies, clinical trials, and manufacturing activities as research and development expenses based on its evaluation of its vendors' progress toward completion of specific tasks. Payment timing may differ significantly from the period in which the costs are recognized as expense. Costs that are paid in advance are deferred as a prepaid expense and amortized over the service period as the services are provided. Costs for services incurred that have not yet been be paid are recognized as accrued expenses.

In estimating the vendors' progress toward completion of specific tasks, the Company uses data such as patient enrollment, clinical site activations or vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services.

Given the number of ongoing preclinical study and clinical trial activities and the subjectivity involved in estimating clinical trial accrued and prepaid expenses, auditing the clinical trial accruals and prepaid expenses involved especially subjective judgment.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to clinical trial accrued and prepaid expenses included the following, among others:

- We tested the design and effectiveness of controls over the estimation of clinical trial accrued and prepaid expenses.
- We obtained and read a sample of research, collaboration, and manufacturing agreements and contracts, as well as amendments thereto.
- We evaluated publicly available information (such as press releases and investor presentations) and board of directors' materials regarding the status of clinical trial and manufacturing activities.
- For a sample of agreements and contracts, we compared the amount of accrual or prepaid expenses at the end of the prior period to current year activity and evaluated the accuracy of the Company's estimation methodology.
- We obtained a written confirmation of the ending inventory balance held at the Company's manufacturing vendor.
- We made selections of specific amounts recognized as research and development expense as well as those recognized as accrued and prepaid expenses to evaluate management's estimate of the vendor's progress and performed the following procedures:
    - Performed corroborating inquiries with Company clinical operations and manufacturing operations personnel.
    - Read the related statement of work, purchase order, or other supporting documentation (such as communications between the Company and vendors).
    - Evaluated management's judgments compared to the evidence obtained.
    - Obtained the listing of all contracts related to research and development expenses to evaluate the completeness of accruals and prepaid expenses.

/s/ *DELOITTE & TOUCHE LLP*

San Jose, California
March 1, 2021

We have served as the Company's auditor since 2013.

ATARA BIOTHERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 200,404	$ 74,317
Short-term investments	300,255	184,792
Restricted cash - short-term	194	194
Accounts receivable	1,250	—
Prepaid expenses and other current assets	21,170	13,689
Total current assets	523,273	272,992
Property and equipment, net	50,517	54,176
Operating lease assets	12,303	14,007
Restricted cash - long-term	1,200	1,200
Other assets	827	567
Total assets	$ 588,120	$ 342,942
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,118	$ 7,963
Accrued compensation	20,458	14,706
Accrued research and development expenses	15,813	8,341
Deferred revenue	33,455	—
Other current liabilities	6,057	5,733
Total current liabilities	82,901	36,743
Deferred revenue - long-term	27,795	—
Operating lease liabilities - long-term	13,041	14,136
Other long-term liabilities	2,044	1,282
Total liabilities	125,781	52,161
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock—$0.0001 par value, 500,000 shares authorized as of December 31, 2020 and 2019, respectively; 83,372 and 56,806 shares issued and outstanding as of December 31, 2020 and 2019, respectively	8	6
Additional paid-in capital	1,586,616	1,108,516
Accumulated other comprehensive income	296	220
Accumulated deficit	(1,124,581)	(817,961)
Total stockholders' equity	462,339	290,781
Total liabilities and stockholders' equity	$ 588,120	$ 342,942

ATARA BIOTHERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)

	Years Ended December 31,		
	2020	2019	2018
Operating expenses:			
Research and development	$ 244,650	$ 216,097	$ 167,457
General and administrative	64,402	79,584	69,654
Total operating expenses	309,052	295,681	237,111
Loss from operations	(309,052)	(295,681)	(237,111)
Interest and other income, net	2,447	4,717	6,368
Loss before provision for income taxes	(306,605)	(290,964)	(230,743)
Provision for (benefit from) income taxes	15	12	(44)
Net loss	$ (306,620)	$ (290,976)	$ (230,699)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities	76	560	(189)
Comprehensive loss	$ (306,544)	$ (290,416)	$ (230,888)
Net loss per common share:			
Basic and diluted net loss per common share	$ (4.15)	$ (5.67)	$ (5.27)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	73,973	51,308	43,811

ATARA BIOTHERAPEUTICS, INC.
Consolidated Statements of Stockholders' Equity
(In thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance as of January 1, 2018	30,730	$ 3	$ 474,662	$ (151)	$ (296,650)	$ 177,864
Issuance of common stock through underwritten offerings, net of offering costs of $526	12,604	2	293,288	—	—	293,290
Issuance of common stock through ATM facilities, net of commissions and offering costs of $1,310	1,008	—	47,586	—	—	47,586
RSU settlements, net of shares withheld	449	—	(7,503)	—	—	(7,503)
Issuance of common stock pursuant to employee stock awards	1,160	—	24,691	—	—	24,691
Stock-based compensation expense	—	—	33,817	—	—	33,817
Net loss	—	—	—	—	(230,699)	(230,699)
Unrealized loss on available-for-sale securities	—	—	—	(189)	—	(189)
Balance as of December 31, 2018	45,951	5	866,541	(340)	(527,349)	338,857
Effect of the adoption of ASC topic 842 (Leases)	—	—	—	—	364	364
Balance as of January 1, 2019	45,951	5	866,541	(340)	(526,985)	339,221
Issuance of common stock and pre-funded warrants through underwritten offering, net of offering costs of $284	6,872	1	140,715	—	—	140,716
Issuance of common stock through ATM facilities, net of commissions and offering costs of $1,553	3,135	—	48,909	—	—	48,909
RSU settlements, net of shares withheld	361	—	(6,695)	—	—	(6,695)
Issuance of common stock pursuant to employee stock awards	487	—	7,350	—	—	7,350
Stock-based compensation expense	—	—	51,696	—	—	51,696
Net loss	—	—	—	—	(290,976)	(290,976)
Unrealized gain on available-for-sale securities	—	—	—	560	—	560
Balance as of December 31, 2019	56,806	6	1,108,516	220	(817,961)	290,781
Issuance of common stock and pre-funded warrants through underwritten offerings, net of offering costs of $583	20,060	2	353,586	—	—	353,588
Issuance of common stock through ATM facilities, net of commissions and offering costs of $1,887	4,786	—	68,004	—	—	68,004
Exercise of pre-funded warrants	57	—	—	—	—	—
RSU settlements, net of shares withheld	1,112	—	(1,521)	—	—	(1,521)
Issuance of common stock pursuant to employee stock awards	551	—	6,680	—	—	6,680
Stock-based compensation expense	—	—	51,351	—	—	51,351
Net loss	—	—	—	—	(306,620)	(306,620)
Unrealized gain on available-for-sale securities	—	—	—	76	—	76
Balance as of December 31, 2020	83,372	$ 8	$ 1,586,616	$ 296	$ (1,124,581)	$ 462,339

ATARA BIOTHERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Operating activities			
Net loss	$ (306,620)	$ (290,976)	$ (230,699)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	51,351	51,696	33,817
Depreciation and amortization expense	8,332	7,070	3,732
Non-cash operating lease expense	1,457	964	—
Amortization (accretion) of investment premiums (discounts)	828	(1,330)	(1,885)
Loss on disposals of property and equipment	130	1,027	—
Asset retirement obligation accretion expense	78	71	49
Non-cash interest expense	—	—	211
Changes in operating assets and liabilities:			
Accounts receivable	(1,250)	—	—
Prepaid expenses and other current assets	(8,666)	(998)	(5,764)
Operating lease assets	886	239	—
Other assets	(219)	322	(314)
Accounts payable	(815)	4,213	(1,958)
Accrued compensation	5,752	4,070	4,972
Accrued research and development expenses	7,472	(10,869)	15,204
Other current liabilities	(187)	(394)	2,491
Deferred revenue	61,250	—	—
Operating lease liabilities	(1,316)	(731)	—
Other long-term liabilities	778	—	372
Net cash used in operating activities	(180,759)	(235,626)	(179,772)
Investing activities			
Purchases of short-term investments	(425,868)	(270,230)	(466,489)
Proceeds from maturities and sales of short-term investments	309,653	336,261	306,125
Purchases of property and equipment	(4,513)	(5,733)	(35,925)
Proceeds from sale of property and equipment	—	161	—
Net cash (used in) provided by investing activities	(120,728)	60,459	(196,289)
Financing activities			
Proceeds from sale of common stock and pre-funded warrants in underwritten offerings, net	353,780	140,888	293,290
Proceeds from issuance of common stock through ATM facilities, net	69,189	47,729	47,586
Proceeds from employee stock awards	6,680	7,350	24,691
Taxes paid related to net share settlement of restricted stock units	(1,521)	(6,695)	(7,503)
Principal payments on finance and capital lease obligations	(389)	(486)	(528)
Other financing activities, net	(165)	—	—
Net cash provided by financing activities	427,574	188,786	357,536
Increase (decrease) in cash, cash equivalents and restricted cash	126,087	13,619	(18,525)
Cash, cash equivalents and restricted cash at beginning of period	75,711	62,092	80,617
Cash, cash equivalents and restricted cash at end of period	$ 201,798	$ 75,711	$ 62,092
Non-cash investing and financing activities			
Property and equipment purchases included in accounts payable and other accrued liabilities	$ 326	$ 276	$ 1,579
Accrued costs related to underwritten public offering	$ 192	$ 172	$ —
Proceeds from issuance of common stock through ATM facilities not yet received	$ —	$ 1,185	$ —
Capitalized lease obligations	$ —	$ —	$ 441
Property and equipment acquired under capital leases	$ —	$ —	$ 191
Asset retirement costs	$ —	$ —	$ 88
Interest capitalized during construction period for build-to-suit lease arrangement	$ —	$ —	$ 77
Supplemental cash flow disclosure			
Cash paid for interest	$ 62	$ 50	$ 240
Cash paid for income taxes	$ 10	$ —	$ —

1. Description of Business

Atara Biotherapeutics, Inc. ("Atara", "we", "our" or "the Company") was incorporated in August 2012 in Delaware. Atara is a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with serious diseases, including solid tumors, hematologic cancers and autoimmune disease.

We have several T-cell immunotherapies in clinical development and are progressing multiple next-generation allogeneic chimeric antigen receptor T-cell ("CAR T") programs. We have entered into a research, development and license agreement ("Bayer License Agreement") with Bayer AG ("Bayer") pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271. See Note 7 for further information.

We have licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center ("MSK"), rights related to our next-generation CAR T programs from MSK and from Moffitt Cancer Center, and rights to know-how and technology from the Council of the Queensland Institute of Medical Research ("QIMR Berghofer"). See Note 6 for further information.

2. Summary of Significant Accounting Policies

Basis of Presentation

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and follow the rules and regulations of the U.S. Securities and Exchange Commission ("SEC").

Principles of Consolidation

The consolidated financial statements include the accounts of Atara and our wholly owned subsidiaries. All intercompany balances and transactions are eliminated in consolidation.

Segment and Geographic Information

We operate and manage our business as one operating and reportable segment, which is the business of developing and commercializing therapeutics. Our Chief Executive Officer, who is our chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Substantially all of our assets are located in the U.S.

Liquidity Risk

We have incurred significant operating losses since inception and have relied primarily on public and private equity financings to fund our operations. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. We expect that existing cash, cash equivalents and short-term investments as of December 31, 2020 will be sufficient to fund our operations for at least the next twelve months from the date of issuance of these financial statements.

Concentration of Credit Risk and Other Uncertainties

We place cash and cash equivalents in the custody of financial institutions that management believes are of high credit quality, the amount of which at times, may be in excess of the amount insured by the Federal Deposit Insurance Corporation. We also make short-term investments in money market funds; U.S. Treasury, government agency and corporate debt obligations; commercial paper; certificates of deposit; and asset-backed securities, which can be subject to certain credit risk. However, we mitigate the risks by investing in high-grade instruments, limiting our exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers.

One research, development and license agreement entered into in 2020 accounted for all of the deferred revenue as of December 31, 2020. For the year ended December 31, 2020, we did not recognize any revenue from this agreement. Our accounts receivable balance consists of amounts due pursuant to this agreement. We believe the receivable balance is fully collectible.

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: our ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, our product candidates, if approved by applicable regulatory authorities; performance of third-party clinical research organizations and manufacturers upon which we rely; development of sales channels; protection of our intellectual property; litigation or claims against us based on intellectual property, patent, product, regulatory or other factors; and our ability to attract and retain employees necessary to support our growth.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions and judgments that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relied upon in preparing these financial statements include estimates related to revenue recognition, clinical study and other accruals, stock-based compensation expense and income taxes. Actual results could differ materially from those estimates.

Leases

On January 1, 2019, we adopted Accounting Standards Update ("ASU") No. 2016-02,*Leases (Topic 842)*. We recorded $14.3 million of operating lease assets and $15.3 million of operating lease liabilities on our consolidated balance sheet as of January 1, 2019 and de-recognized the build-to-suit asset and corresponding lease obligation of $10.3 million for our Thousand Oaks manufacturing facility lease. The transition method we elected for adoption included recording a cumulative effect adjustment to retained earnings as of January 1, 2019, which was not material.

We determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets, other current liabilities, and operating lease liabilities on our consolidated balance sheets. Leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize short-term lease expense for these leases on a straight-line basis over the lease term. Finance leases are included in other assets, other current liabilities, and other long-term liabilities on our consolidated balance sheets.

Lease assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The lease term includes renewal options that we are reasonably certain of exercising as of the commencement date. None of the lease terms used to calculate the future minimum lease payments at commencement date include renewal options. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The incremental borrowing rate for our leases is determined based on lease term and currency in which lease payments are made, adjusted for impacts of collateral. Lease assets also includes any lease payments made and excludes lease incentives and initial direct costs incurred. Operating lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Finance lease assets are amortized over the shorter of the lease term or the asset's estimated useful life.

Our facilities and equipment operating leases have lease and non-lease components and we have made a policy election to account for the lease and non-lease components as a single lease component.

Through December 31, 2018, the leases were reviewed for classification as operating, capital or build-to-suit leases. For operating leases, rent was recognized on a straight-line basis over the lease period. For capital leases, we recorded the leased asset in property and equipment, net, with the related amortization of the capital lease asset recorded in depreciation expense, and we recorded a corresponding liability for principal and interest. Payments were recorded as reductions to these liabilities with interest being charged to interest expense in our consolidated statements of operations and comprehensive loss.

We analyzed the nature of the renovations and our involvement during the construction period of our manufacturing facility and determined that we were the deemed "owner" of the construction project during the construction period. As a result, we were required to capitalize the fair value of the building as well as the construction costs incurred on our consolidated balance sheet along with a corresponding financing liability for landlord-paid construction costs (i.e., "build-to-suit" accounting).

Once construction was complete, the Company considered the requirements for sale-leaseback accounting treatment, including evaluating whether all risks of ownership have been transferred back to the landlord, as evidenced by a lack of continuing involvement in the leased property. Since the arrangement did not qualify for sale-leaseback accounting treatment, the building asset remained on the Company's consolidated balance sheets at its historical cost, and such asset was depreciated over its estimated useful life. The Company bifurcated its lease payments into a portion allocated to the building and a portion allocated to the parcel of land on which the building has been built. The portion of the lease payments allocated to the land was treated for accounting purposes as operating lease payments, and therefore was recorded as rent expense in the consolidated statements of operations and comprehensive loss. The portion of the lease payments allocated to the building was further bifurcated into a portion allocated to interest expense and a portion allocated to reduce the build-to-suit lease obligation. The initial recording of these assets and liabilities were classified as non-cash investing and financing items, respectively, for purposes of the consolidated statements of cash flows. The build-to-suit asset and corresponding lease obligation was derecognized upon adoption of the new lease standard as we did not control the building during the construction period. See Note 8 for further information.

Asset Retirement Obligations ("ARO")

ARO are legal obligations associated with the retirement of long-lived assets pertaining to leasehold improvements. These liabilities are initially recorded at fair value and the related asset retirement costs are capitalized by increasing the carrying amount of the related assets by the same amount as the liability. Asset retirement costs are subsequently depreciated over the useful lives of the related assets. Subsequent to initial recognition, the Company records period-to-period changes in the ARO liability resulting from the passage of time and revisions to either the timing or the amount of the original estimate of undiscounted cash flows. The Company derecognizes ARO liabilities when the related obligations are settled.

Foreign Currency

Transactions and monetary assets and liabilities that are denominated in a foreign currency are translated into U.S. dollars at the current exchange rate on the transaction date and as of each balance sheet date, respectively, with gains or losses on foreign exchange changes recognized in interest and other income (expense), net in the consolidated statements of operations and comprehensive loss. Foreign currency-denominated monetary assets and liabilities as of December 31, 2020 were not material.

Cash Equivalents and Short-Term Investments

Cash equivalents are defined as short-term, highly liquid investments with original maturities of90 days or less at the date of purchase, and generally consist of money market funds, U.S. Treasury, government agency and corporate debt obligations, and commercial paper.

Investments with original maturities of greater than90 days are classified as short-term investments on the balance sheet, and consist primarily of U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities.

As our entire investment portfolio is considered available for use in current operations, we classify all investments as available-for-sale and as current assets, even though the stated maturity may be more than one year from the current balance sheet date. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported in accumulated other comprehensive loss, which is a separate component of stockholders' equity in the consolidated balance sheet.

The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity, which are both recorded to interest and other income (expense), net in the consolidated statements of operations and comprehensive loss.

Changes in the fair value of available-for-sale securities impact the consolidated statements of operations and comprehensive loss only when such securities are sold, if an allowance for credit losses is recognized or if an impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. We regularly review our investment portfolio to determine if any security is impaired, which would require us to record an allowance for credit losses or impairment charge in the period any such determination is made. In making this judgment, we evaluate, among other things, the duration and extent to which the fair value of a security is less than its cost, our intent to sell or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis, the financial condition of the issuer and any changes thereto, and, as necessary, the portion of a decline in fair value that is credit-related. This assessment could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses, allowances for credit losses and impairments on available-for-sale securities, if any, are recorded to interest and other income, net in the statements of operations and comprehensive loss.

Fair Value Measurement

The carrying amounts of certain of our financial instruments including cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. Short-term investments are comprised of available-for-sale securities, which are carried at fair value.

Fair Value of Financial Instruments

Our financial assets are measured at fair valueon a recurring basis using the following hierarchy to prioritize valuation inputs, in accordance with applicable GAAP:

Level 1: Quoted prices in active markets for identical assets or liabilities that we have the ability to access

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data such as quoted prices, interest rates and yield curves

Level 3: Inputs that are unobservable data points that are not corroborated by market data

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs. There have been no transfers between Level 1, Level 2, and Level 3 in any periods presented.

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. U.S. Treasury, government agency and corporate debt obligations, commercial paper and asset-backed securities are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. We have no Level 3 financial assets or liabilities.

Property and Equipment, net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, ranging fromthree to five years. Costs incurred to acquire, construct or install property and equipment during the construction stage of a capital project or costs incurred to purchase and develop internal use software during the application development stage are recorded as construction in progress. Leasehold improvements are amortized over the lesser of the life of the leasehold improvements or the lease term. Maintenance and repairs are charged to operations as incurred.

Long-lived Assets

We evaluate the carrying amount of our long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. To date, there have been no such impairment losses.

Stock-Based Compensation Expense

We account for stock-based compensation expense, including the expense of restricted common stock awards (“RSAs”), grants of restricted stock units (“RSUs”), and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant. The fair value for our RSAs is their intrinsic value, which is the difference between the fair value of the underlying stock at the measurement date and the purchase price. The fair value of our RSUs is the fair value of the underlying stock at the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model. For awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and begin to recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. Stock-based compensation expense for awards with time-based vesting criteria is recognized as expense on a straight-line basis over the requisite service period. Stock-based compensation expense for awards with performance and other vesting criteria is recognized as expense under an accelerated graded vesting model.

Key assumptions used in the Black-Scholes valuation model used for employee stock awards include:

Expected term – We derived the expected term using the "simplified" method (the expected term is determined as the average of the time-to-vesting and the contractual life of the options), as we have limited historical information to develop expectations about future exercise patterns and post vesting employment termination behavior.

Expected volatility – Expected volatility is estimated using comparable public companies' volatility for similar terms.

Expected dividend – We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore, we assumed an expected dividend yield of 0%.

Risk-free interest rate – The risk-free interest rate is based on the yield on U.S. Treasury securities with the expected term of the associated award.

The fair value of our common stock is based on observable market prices.We account for forfeitures of stock-based awards as they occur.

Revenue Recognition

At inception, we determine whether contracts are within the scope of Accounting Standards Codification Topic 606 (ASU No. 2014-09),*Revenue from Contracts with Customers*, and all subsequent amendments (collectively, "ASC 606") or other topics. For contracts that are determined to be within the scope of ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods and services. To achieve this core principle, we apply the following five steps (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as we satisfy a performance obligation. We only apply the five-step model to contracts when we determine that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, we apply judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

The transaction price is determined based on the consideration to which we will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment, which is discussed in further detail for our research and license agreement in Note 7. Our research and license agreement did not contain a significant financing component.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative standalone selling prices. We typically determine standalone selling prices using an adjusted market assessment approach model.

We satisfy performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by our performance, (ii) our performance creates or enhances an asset that the customer controls as the asset is created or enhanced or (iii) our performance does not create an asset with an alternative use to the entity and we have an enforceable right to payment for performance completed to date. If we do not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring control of a promised good or service to a customer. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

As of December 31, 2020, our deferred revenue is related to the Bayer License Agreement, which is within the scope of ASC 606. As discussed in further detail in Note 7, the terms of this arrangement include potential payments to us for the following: nonrefundable, upfront fees; development, regulatory, and commercial milestone payments; research and development funding payments; and royalties on the net sales of licensed products. These payments relate to promised goods or services for which revenue will be recognized upon our satisfaction of the underlying performance obligations.

Licenses of intellectual property: If the license of our intellectual property is determined to be distinct from the other performance obligations identified in an arrangement, we recognize revenues from consideration allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are combined with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue.

Milestone payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates the probability of reaching the milestones and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a significant reversal of revenue would not be probable. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration and license revenues and the consolidated statements of operations and comprehensive loss in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on levels of sales, if the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied. To date, we have not recognized any royalty revenue resulting from the Bayer License Agreement.

We receive payments from our customer based on billing schedules established in each contract. Our contract liabilities consist of deferred revenue. Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the we have satisfied our obligations under these arrangements.

Certain judgments affect the application of our revenue recognition policy. For example, we record short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months, and long-term deferred revenue consists of amounts that we do not expect will be recognized in the next 12 months. This estimate is based on our current operating plan and, if our operating plan should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

Contract Balances

Customer payments are recorded as deferred revenue upon receipt or when invoiced and may require deferral of revenue recognition to a future period until we satisfy its performance obligations under these arrangements. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional.

Research and Development Expense

Research and development expense consists of costs incurred in performing research and development activities, including compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical and preclinical studies; the costs of acquiring and manufacturing clinical study materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs, and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

Clinical Study Accruals

Costs for preclinical studies, clinical studies and manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

Defined Contribution Plan

We have one qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. Beginning in 2019, we make matching contributions, equal to 50% of each dollar contributed up to the first6% of an individual's eligible earnings, up to the annual IRS maximum. For the years ended December 31, 2020 and 2019, we recorded matching contributions of approximately $2.1 million and $1.6 million, respectively.

Other Current Liabilities

Other current liabilities consisted of the following as of each period end:

	December 31, 2020	December 31, 2019
	(in thousands)	
Accrued operating expenses	$ 3,016	$ 3,900
Current portion of operating lease liabilities	1,730	1,312
Current portion of finance lease liabilities	255	269
Other accrued liabilities	1,056	252
Total other current liabilities	$ 6,057	$ 5,733

Income Taxes

We use the asset and liability method to account for income taxes. We record deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect when the differences are expected to reverse. Valuation allowances are provided when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized. Based on the available evidence, we are unable, at this time, to support the determination that it is more likely than not that our deferred tax assets will be utilized in the future. Accordingly, we recorded a full valuation allowance as of December 31, 2020 and 2019. We intend to maintain valuation allowances until sufficient evidence exists to support their reversal.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period resulting from transactions from non-owner sources. Our other comprehensive income (loss) is comprised solely of unrealized gains (losses) on available-for-sale securities and is presented net of taxes. We have not recorded any reclassifications from other comprehensive income (loss) to net loss during any period presented.

Recent Accounting Pronouncements

The Company considers the applicability and impact of any ASUs issued by the Financial Accounting Standards Board ("FASB"). Other than the ASUs we adopted effective January 1, 2020 and listed below, all other ASUs were assessed and determined to be either not applicable or are expected to have minimal impact on our consolidated financial statements.

Adoption of New Accounting Pronouncements

We adopted ASU No. 2016-13 (as amended by ASUs 2018-19, 2019-04, 2019-05 and 2019-11), *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, prospectively on January 1, 2020. Under this new guidance, a company is required to estimate credit losses on certain types of financial instruments using an expected-loss model, replacing the current incurred-loss model, and record the estimate through an allowance for credit losses. We do not hold material amounts of the types of financial instruments impacted by this guidance on our balance sheet. The guidance also establishes a new impairment model for available-for-sale debt securities. The adoption did not have a material impact on our consolidated balance sheet or our consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years ended December 31, 2020, 2019 and 2018.

We adopted ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, effective January 1, 2020, electing a prospective adoption method. The new standard requires that certain implementation costs for cloud computing arrangements are capitalized and amortized over the term of associated hosted cloud computing arrangement service. Capitalized implementation costs are classified in prepaid expenses and other assets. The amortization of the capitalized asset is presented in the same line on the statement of operations and comprehensive loss as the fees for the associated hosted cloud computing arrangement service and not included with depreciation or amortization expense related to property and equipment or intangible assets. Cash flows related to capitalized implementation costs are presented in cash flows used in operating activities. The adoption did not have a material impact on our consolidated balance sheet or our consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years ended December 31, 2020, 2019 and 2018.

We adopted ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as of January 1, 2020, which eliminates certain exceptions related to the general principles in ASC 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The provisions of the ASU that are applicable to Atara are applied on a prospective basis. The adoption did not have a material impact on our consolidated balance sheet or our consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years ended December 31, 2020, 2019 and 2018.

3. Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of shares of common stock and pre-funded warrants outstanding during the period, without consideration of common share equivalents. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock, pre-funded warrants and common share equivalents outstanding for the period. The pre-funded warrants are included in the computation of basic and diluted net loss per common share as the exercise price is negligible and the pre-funded warrants are fully vested and exercisable. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potential dilutive securities, which include unvested restricted stock units ("RSUs"), unvested performance-based RSUs for which established performance criteria have been achieved as of the end of the respective periods, vested and unvested options to purchase common stock and shares to be issued under our employee stock purchase plan ("ESPP"), have been excluded from the computation of diluted net loss per share as the effect is antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following table represents the potential common shares issuable pursuant to outstanding securities as of the related period end dates that were excluded from the computation of diluted net loss per common share, as their inclusion would have an antidilutive effect:

	As of December 31,		
	2020	2019	2018
Unvested RSUs	2,868,407	1,910,764	1,405,460
Vested and unvested options	7,832,386	6,934,262	6,276,999
ESPP share purchase rights	26,349	20,438	7,974
Total	10,727,142	8,865,464	7,690,433

4. Financial Instruments

The following tables summarize the estimated fair value and related valuation input hierarchy of our available-for-sale securities as of each period end:

As of December 31, 2020:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	$ 168,343	$ —	$ —	$ 168,343
U.S. Treasury obligations	Level 2	230,239	113	(6)	230,346
Government agency obligations	Level 2	22,537	22	(3)	22,556
Corporate debt obligations	Level 2	50,080	166	(1)	50,245
Commercial paper	Level 2	17,990	—	—	17,990
Asset-backed securities	Level 2	9,860	10	(5)	9,865
Total available-for-sale securities		499,049	311	(15)	499,345
Less: amounts classified as cash equivalents		(199,090)	—	—	(199,090)
Amounts classified as short-term investments		$ 299,959	$ 311	$ (15)	$ 300,255

As of December 31, 2019:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	$ 63,554	$ —	$ —	$ 63,554
U.S. Treasury obligations	Level 2	52,805	46	(1)	52,850
Government agency obligations	Level 2	6,151	1	(1)	6,151
Corporate debt obligations	Level 2	100,512	180	(10)	100,682
Commercial paper	Level 2	26,290	—	—	26,290
Asset-backed securities	Level 2	7,266	6	—	7,272
Certificate of deposit	Level 2	500	—	—	500
Total available-for-sale securities		257,078	233	(12)	257,299
Less: amounts classified as cash equivalents		(72,507)	—	—	(72,507)
Amounts classified as short-term investments		$ 184,571	$ 233	$ (12)	$ 184,792

The amortized cost and fair value of our available-for-sale securities by contractual maturity were as follows:

	As of December 31, 2020		As of December 31, 2019	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	$ 434,828	$ 435,023	$ 214,085	$ 214,199
Maturing in one to five years	64,221	64,322	42,993	43,100
Total available-for-sale securities	$ 499,049	$ 499,345	$ 257,078	$ 257,299

As of December 31, 2020, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the available-for-sale securities we hold, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. We considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and determined that our investments were not significantly impacted. For all securities with a fair value less than its amortized cost basis, we determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. During the years ended December 31, 2020, 2019 and 2018, we did not recognize any impairment losses on our investments.

We have elected the practical expedient to exclude the applicable accrued interest from both the fair value and the amortized cost basis of our available-for-sale securities for purposes of identifying and measuring an impairment. We present accrued interest receivable related to our available-for-sale securities in prepaid expenses and other current assets, separate from short-term investments on our consolidated balance sheet. As of December 31, 2020 and 2019, accrued interest receivable was $0.7 million and $0.9 million, respectively. Our accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which we consider to be in the period in which we determine the accrued interest will not be collected by us. We have not written off any accrued interest receivables for the years ended December 31, 2020, 2019 and 2018.

In addition, restricted cash collateralized by money market funds is a financial asset measured at fair value and is a Level 1 financial instrument under the fair value hierarchy. As of December 31, 2020 and 2019, restricted cash totaled $1.4 million.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the consolidated balance sheets that sum to the total of the same such amounts in the consolidated statement of cash flows:

	December 31, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 200,404	$ 74,317
Restricted cash - short-term	194	194
Restricted cash - long-term	1,200	1,200
Total cash, cash equivalents and restricted cash	$ 201,798	$ 75,711

5. Property and Equipment

Property and equipment consisted of the following as of each period end:

	December 31, 2020	December 31, 2019
	(in thousands)	
Leasehold improvements	$ 50,132	$ 49,028
Lab equipment	8,033	6,815
Machinery and equipment	5,023	3,832
Computer equipment and software	4,060	3,299
Furniture and fixtures	2,066	1,764
Construction in progress	879	1,116
Property and equipment, gross	70,193	65,854
Less: accumulated depreciation and amortization	(19,676)	(11,678)
Property and equipment, net	$ 50,517	$ 54,176

Depreciation and amortization expense was $8.3 million, $7.1 million and $3.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

6. License, Collaboration and Manufacturing Agreements

MSK Agreements – In June 2015, we entered into an exclusive license agreement with MSK for three clinical stage T-cell therapies. We are required to make payments of up to $33.0 million to MSK based on achievement of specified regulatory and sales-related milestones, as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any. In addition, under certain circumstances, we are required to make certain minimum annual royalty payments to MSK, which are creditable against earned royalties owed for the same annual period. We are also required to pay a low double-digit percentage of any consideration we receive for sublicensing the licensed rights. The license agreement expires on a product-by-product and country-by-country basis on the latest of: (i) expiration of the last licensed patent rights related to each licensed product, (ii) expiration of any market exclusivity period granted by law with respect to each licensed product, and (iii) a specified number of years after the first commercial sale of the licensed product in each country. Upon expiration of the license agreement, Atara will retain non-exclusive rights to the licensed products.

In May and December 2018, we licensed additional technology from MSK. In connection with the effectiveness of the December 2018 license agreement, we made upfront cash payments of $12.5 million in first quarter of 2019, which were recorded as research and development expense in our consolidated statement of operations and comprehensive loss in the fourth quarter of 2018. We are obligated to make additional milestone payments based on achievement of specified development, regulatory and sales-related milestones as well as mid-single-digit percentage tiered royalty payments based on future sales of products resulting from the development of the licensed product candidates, if any.

QIMR Berghofer Agreements – In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer. Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology that we exercised in June 2018. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019 to terminate our license to certain rights related to cytomegalovirus and again in August 2020 to terminate our license to certain rights related to BK polyomavirus and JC polyomavirus. Our current license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any. Under the terms of our current research and development collaboration agreement, we are also required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. These payments are expensed on a straight-line basis over the related development periods. The agreement also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones.

From time to time, we have entered into other license and collaboration agreements with other parties. For example, we licensed additional rights related to our MSK-partnered next-generation CAR T programs from MSK in May 2018 and we licensed rights related to our next-generation CAR T programs from Moffitt Cancer Center in August 2018, and we agreed to collaborate through sponsored research in connection with each of these licenses. We also licensed rights related to our MSK-partnered next-generation CAR T programs from the National Institutes of Health in December 2018.

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when it is probable that the milestones will be achieved or royalties are due. As of December 31, 2020 and 2019, there were no outstanding obligations for milestones and royalties under our license and collaboration agreements.

Cognate Agreement – In December 2019, we entered into a Commercial Manufacturing Services Agreement (the "Manufacturing Agreement") with Cognate Bioservices, Inc. ("Cognate"). Pursuant to the Manufacturing Agreement, Cognate provides manufacturing services for certain of our product candidates. The initial term of the Manufacturing Agreement is from January 1, 2020 until December 31, 2021 and is renewable with Cognate's approval for an additional one-year period. We may terminate the Manufacturing Agreement for convenience on six months' written notice to Cognate, or immediately if Cognate is unable to perform the services under the Manufacturing Agreement or fails to obtain or maintain certain necessary approvals.

7. Research, Development and License Agreement

In December 2020, we entered into the Bayer License Agreement to develop mesothelin-directed CAR T-cell therapies for the treatment of solid tumors, pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271 (the "Licensed Products").

Under the terms of the Bayer License Agreement, we will be responsible at our cost for all mutually agreed preclinical and clinical activities for ATA2271 through the first in human Phase 1 clinical study in collaboration with MSK, following which Bayer will be responsible for the further development of ATA2271 at its cost. Bayer will be responsible for the development of ATA3271, except for certain mutually agreed preclinical, translational, manufacturing and supply chain activities to be performed by us relating to ATA3271, in each case at Bayer's cost. Bayer will also be solely responsible for commercializing the Licensed Products at its cost.

In December 2020, we received an upfront cash payment of $45.0 million from Bayer for the exclusive license grant, net of applicable withholding taxes, which we believe are recoverable, and an additional $15.0 million upfront reimbursement payment for certain research and process development activities to be performed by us. We are also entitled to receive (i) up to an additional $5.0 million for additional, specified translational activities under the Bayer License Agreement, of which we have invoiced $1.3 million, and (ii) an aggregate of up to $610.0 million in milestone payments upon achieving certain development, regulatory and commercial milestones relating to the Licensed Products. In addition, we are eligible to receive from Bayer tiered royalties at percentages up to low double digits on worldwide net product sales of the Licensed Products on a country-by-country and product-by-product basis until the later of 12 years after the first commercial sale in such country or the expiration of specified patent rights in such country, subject to certain reductions and aggregate minimum floors.

We will negotiate a separate manufacturing and supply agreement with Bayer for us to manufacture allogeneic mesothelin-directed CAR T-cell therapies for Bayer to use in clinical trials at a price based on our costs plus a margin, which is consistent with our standalone selling price. Bayer and we have formed a joint steering committee ("JSC") that will provide oversight, decision making and implementation guidance regarding the collaboration activities covered under the agreement.

We assessed this arrangement in accordance with ASC 606 and concluded that the promises in the Bayer License Agreement represent transactions with a customer. We concluded that the Bayer License Agreement contains the following promises: (i) a development and commercialization license; (ii) performance of early-stage research and development ("R&D") services, including technology transfer services; (iii) JSC participation; and (iv) chemistry, manufacturing and control ("CMC") services. In accordance with ASC 606, we determined that the license, early-stage R&D and CMC services were not distinct from each other, as the license, early-stage R&D and CMC services are highly interdependent upon one another. Participation on the JSC to oversee the research and development activities are combined into the single performance obligation as these activities are highly interdependent with the other R&D and CMC services. Accordingly, we determined that these promises should be combined into a single performance obligation.

Under the Bayer License Agreement, in order to evaluate the appropriate transaction price, we determined that the $5.0 million upfront payment for the license, $15.0 million for certain research and process development activities and the $5.0 million for additional specified translational activities, to be billed based on certain criteria being met, constituted the entire consideration to be included in the transaction price at the outset of the arrangement, and this amount was allocated to the single performance obligation. The potential development and commercial milestone payments that we are eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. None of the future royalty and sales-based milestone payments were included in the transaction price, as the potential payments represent sales-based consideration. We will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust our estimate of the transaction price.

We will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period, as we determined the cost-based input method to be the best measure of progress, as other measures do not reflect how we transfer our performance obligation to Bayer. In applying the cost-based input method of revenue recognition, revenue will be recognized based on the amount of actual costs incurred relative to the total budgeted costs expected to be incurred for the combined performance obligation. A cost-based input method of revenue recognition requires us to make estimates of costs to complete our performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. Revenue associated with the combined performance obligation is being recognized over the initial estimated contract term of three years. The transfer of control occurs over this time period and, in our judgment, is the best measure of progress towards satisfying the performance obligation. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

During the year ended December 31, 2020, we didnot recognize any revenue under Bayer License Agreement. Deferred revenue related to the agreement with Bayer amounted to $61.3 million as of December 31, 2020, of which $33.5 million is included in current liabilities and $27.8 million is included in long-term liabilities, is expected to be recognized over the next three years. No development or sales-based milestone payments were received during the year ended December 31, 2020.

8. Leases

We lease our corporate headquarters in South San Francisco, California under a non-cancellable lease agreement that expires in May 2022 and for which we have an option to extend the lease for an additional five years. In connection with the lease, we are required to maintain a letter of credit in the amount of $0.2 million to the landlord, which expires and is renewed every 12 months, and is classified as restricted cash in our consolidated balance sheet. In November 2018, we entered into a lease agreement for additional office space in Thousand Oaks, California that expires in February 2026 and for which we have the option to extend the lease for an additional period offive years after the initial term. Additionally, we entered into a new lease for our office and lab space in Aurora, Colorado, effective May 2019, that expires in April 2024.

In February 2017, we entered into a lease agreement for approximately90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California. The initial 15-year term of the lease commenced on February 15, 2018, upon the substantial completion of landlord's work as defined under the agreement. The contractual obligations during the initial term are $16.4 million in aggregate. We have the option to extend the lease for two additional periods of ten andnine years, respectively, after the initial term. In connection with the lease, we were required to issue a letter of credit in the amount of $1.2 million to the landlord, which is recorded as long-term restricted cash in our consolidated balance sheet.

Based on the terms of the lease agreement and on our involvement in certain aspects of the construction, we were deemed the owner of the building during the construction period in accordance with U.S. GAAP in effect prior to January 1, 2019. Under this build-to-suit lease arrangement, we recognized construction in progress based on all construction costs incurred by both us and the landlord. We also recognized a financing obligation equal to all costs funded by the landlord.

Due to completion of the construction by the landlord and not having met the criteria for sale-lease back accounting, we transferred the $10.3 million of landlord's construction costs previously capitalized as construction in progress to a build-to-suit asset, and recognized a corresponding long-term financing obligation for the same amount in long-term liabilities in our consolidated balance sheets. In addition, we recorded $0.3 million of capitalized interest during the construction period through December 31, 2018. A portion of the monthly lease payment was allocated to land rent and recorded as an operating lease expense and the non-interest portion of the amortized lease payments to the landlord related to rent of the building was applied to the lease financing liability. Further, we recorded ground lease expense of $0.4 million for the year ended December 31, 2018 in our consolidated statement of operations and comprehensive loss, representing the estimated cost of renting the land during the construction period. Due to the adoption of ASU No. 2016-02, Leases (Topic 842), no ground lease expense was recognized for the years ended December 31, 2020 and 2019.

The maturities of lease liabilities under our operating and finance leases as of December 31, 2020 were as follows:

	Operating Leases	Finance Leases
Years Ending December 31,	(in thousands)	
2021	$ 3,177	$ 282
2022	2,835	130
2023	2,696	29
2024	2,593	—
2025	2,587	—
Thereafter	9,300	—
Total lease payments	$ 23,188	$ 441
Less: amount representing interest	(8,417)	(37)
Present value of lease liabilities	$ 14,771	$ 404
Balance as of December 31, 2020		
Other current liabilities	$ 1,730	$ 255
Operating lease liabilities - long-term	13,041	—
Other long-term liabilities	—	149
Total	$ 14,771	$ 404

The components of lease cost were as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
	(in thousands)	
Operating lease cost:		
Operating lease cost	$ 3,020	$ 2,578
Short-term lease cost	987	770
Total operating lease cost	$ 4,007	$ 3,348
Finance lease cost:		
Amortization expense	$ 389	$ 324
Interest on lease liabilities	60	56
Total finance lease cost	$ 449	$ 380

Rent expense under operating leases for the year ended December 31, 2018 was $2.2 million.

Other information related to leases was as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
	(in thousands, except lease term and discount rate)	
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 2,878	$ 2,346
Operating cash flows for finance leases	62	50
Financing cash flows for finance leases	389	486
Operating lease assets obtained in exchange for lease obligations:	$ —	$ 838
Finance lease assets obtained in exchange for lease obligations:	281	323
Non-cash increase to operating lease assets due to remeasurement of lease liabilities:	639	—
Weighted Average Remaining Lease Term		
Operating leases	9.4 years	10.3 years
Finance leases	1.7 years	2.5 years
Weighted Average Discount Rate		
Operating leases	10.3 %	10.4 %
Finance leases	9.7 %	10.0 %

Asset Retirement Obligation

The Company's ARO consists of a contractual requirement to remove the tenant improvements at our manufacturing facility in Thousand Oaks, California and restore the facility to a condition specified in the lease agreement. The Company records an estimate of the fair value of its ARO in long-term liabilities in the period incurred. The fair value of the ARO is also capitalized in property and equipment, net and depreciated over the lease term. The fair value of our ARO was estimated by discounting projected cash flows over the estimated life of the related assets using our credit adjusted risk-free rate.

The following table presents the activity for our ARO liabilities:

	ARO Liability (In thousands)
Balance as of December 31, 2019	$ 788
Accretion expense	78
Balance as of December 31, 2020	$ 866

9. Commitments and Contingencies

License and Collaboration Agreements

Potential payments related to our license and collaboration agreements, including milestone and royalty payments, are detailed in Note 6.

Other Research and Development Agreements

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination on notice. As of December 31, 2020 and 2019, there were no amounts accrued related to termination charges for minimum purchase volumes not being met.

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we consider the fair value of these indemnification agreements to be minimal. Accordingly, we did not record liabilities for these agreements as of December 31, 2020 and 2019.

Contingencies

From time to time, we may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business or otherwise. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us because of the defense costs, diversion of management resources and other factors. We are not currently involved in any material legal proceedings.

10. Stockholders' Equity

Our authorized capital stock consists of 520,000,000 shares, all with a par value of $0.0001 per share, of which 500,000,000 shares are designated as common stock and 20,000,000 shares are designated as preferred stock. There were no shares of preferred stock outstanding as of December 31, 2020 and 2019.

Equity Offerings

In January 2018, we completed an underwritten public offering of 7,675,072 shares of common stock at an offering price of $18.25 per share and received net proceeds of $131.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us. Further, in March 2018, we completed an underwritten public offering of 4,928,571 shares of common stock at an offering price of $35.00 per share and received net proceeds of $161.9 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

In July 2019, we issued and sold 6,871,727 shares of common stock at a public offering price of $15.28 per share and pre-funded warrants to purchase 2,945,026 shares of common stock at an offering price of $15.2799 per warrant in an underwritten public offering pursuant to a shelf registration on Form S-3. The gross proceeds from this public offering were $150.0 million, resulting in aggregate net proceeds of $140.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Each pre-funded warrant entitles the holder to purchase one share of common stock at an exercise price of $0.0001 per share and expires seven years from the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise ("Maximum Ownership Percentage"). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. As of December 31, 2020, 2,888,526 of the pre-funded warrants from the July 2019 underwritten public offering were outstanding.

In the second quarter of 2020, we issued and sold 12,633,039 shares of common stock at a public offering price of $11.32 per share and pre-funded warrants to purchase 2,866,961 shares of common stock at a public offering price of $11.3199 per warrant in an underwritten public offering pursuant to a shelf registration on Form S-3. We granted the underwriters an option to purchase up to 2,325,000 additional shares of our common stock at a public offering price of $11.32, less underwriting discounts and commissions. The full option was exercised by the underwriters in June 2020. The gross proceeds from this public offering were $201.8 million, resulting in net proceeds of $189.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us. The terms of the pre-funded warrants issued and sold as part of this public offering were similar to those above.

In December 2020, we issued and sold 5,102,041 shares of common stock at a public offering price of $24.50 per share and pre-funded warrants to purchase 2,040,816 shares of common stock at a public offering price of $24.4999 per warrant in an underwritten public offering pursuant to a shelf registration on Form S-3. The gross proceeds from this public offering were $175.0 million, resulting in net proceeds of $164.3 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of December 31, 2020, all of the pre-funded warrants issued and sold as part of the 2020 underwritten public offerings were outstanding.

ATM Facilities

In March 2017, we entered into a sales agreement (the "2017 ATM Facility") with Cowen and Company, LLC ("Cowen"), which provided for the sale, in our sole discretion, of shares of our common stock, in the aggregate offering price of up to $75.0 million through Cowen, as our sales agent. We paid a commission of up to 3.0% of the gross sales proceeds of any common stock sold under the 2017 ATM Facility.

In February 2019, we terminated the 2017 ATM Facility and entered into a new sales agreement (the "2019 ATM Facility") with Cowen, which provided for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. We paid a commission of up to 3.0% of gross sales proceeds of the common stock sold under the 2019 ATM Facility.

In February 2020, we entered into a new sales agreement (the "2020 ATM Facility") with Cowen, which provides for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million through Cowen, as our sales agent. The 2020 ATM Facility is separate from and does not replace the 2019 ATM Facility in any way. We pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2020 ATM Facility.

During the fiscal year ended December 31, 2020, we sold an aggregate of 4,785,514 shares of common stock under the ATM facilities, at an average price of $14.60 per share, for gross proceeds of $69.9 million and net proceeds of $68.0 million, after deducting commissions and other offering expenses payable by us. During the fiscal year ended December 31, 2019, we sold an aggregate of 3,135,347 shares of common stock under the 2019 ATM Facility, at an average price of $16.09 per share, for gross proceeds of $50.5 million and net proceeds of $48.9 million, after deducting commissions and other offering expenses payable by us. Approximately $1.2 million of the $48.9 million net proceeds was received on January 3, 2020. The issuance and sale of these shares by us pursuant to the ATM facilities are deemed "at the market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), and are registered under the Securities Act.

As of December 31, 2020, we had fully utilized the 2019 ATM Facility, and $79.7 million of common stock remained available to be sold under the 2020 ATM Facility, subject to certain conditions as specified in the agreement.

Equity Incentive Plans

In March 2014, we adopted the 2014 Equity Incentive Plan ("2014 EIP"), which was amended and restated on October 15, 2014 upon the pricing of our initial public offering ("IPO").

The 2014 EIP provides for annual increases in the number of shares available for issuance thereunder on the first business day of each fiscal year, beginning with 2015 and ending in 2024, equal to five percent of the number of shares of the Company's common stock outstanding as of such date or a lesser number of shares as determined by our board of directors.

Under the terms of the 2014 EIP, we may grant stock options, RSAs and RSUs to employees, directors, consultants and other service providers. RSUs generally vest over four years. In 2020, we granted performance-based awards to certain of our employees that provide for the issuance of common stock if specified Company performance criteria related to our clinical programs are achieved. The number of performance-based awards that ultimately vests depends upon if, when and which performance criteria are achieved, as well as the employee's continuous service, as defined in the 2014 EIP, through the date of vesting. The fair value of RSUs, including those with performance conditions, is determined as the closing stock price on the date of grant. Stock options are granted at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an option granted to a 10% shareholder cannot be less than 110% of the estimated fair value of the shares on the date of grant. Options granted generally vest over four years and expire in seven to ten years. As of December 31, 2020, a total of 13,545,106 shares of common stock were reserved for issuance under the 2014 EIP, of which 2,764,225 shares were available for future grant and 10,780,881 shares were subject to outstanding options and RSUs, including performance-based awards.

In February 2018, we adopted the 2018 Inducement Plan ("Inducement Plan"), under which we may grant options, stock appreciation rights, RSAs and RSUs to new employees. In September 2020, we amended the Inducement Plan to reserve an additional 1,500,000 shares of the Company's common stock for issuance under the Inducement Plan, as amended. As of December 31, 2020, 2,634,836 shares of common stock were reserved for issuance under the Inducement Plan, of which 1,734,211 shares were available for future grant and 900,625 shares were subject to outstanding options and RSUs.

Restricted Stock Units

The weighted average grant date fair value of RSUs granted during the years ended December 31, 2020, 2019 and 2018 was $12.19, $27.04 and $36.83, respectively. The estimated fair value of RSUs that vested in the years ended December 31, 2020, 2019 and 2018 was $23.6 million, $13.8 million and $10.8 million, respectively. As of December 31, 2020, there was $39.4 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.3 years. This excludes unrecognized stock-based compensation expense for performance-based RSUs that were deemed not probable of vesting in accordance with U.S. GAAP. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2020 was $75.2 million.

The following is a summary of RSU activity under our 2014 EIP and Inducement Plan:

	RSUs	
	Shares	Weighted Average Grant Date Fair Value
Balance as of December 31, 2019	1,910,764	$ 26.93
Granted	3,973,991	$ 12.19
Forfeited	(836,190)	$ 18.39
Vested	(1,218,945)	$ 19.34
Balance as of December 31, 2020	3,829,620	$ 15.91

Under our RSU settlement procedures, for some of the RSUs granted to our employees, we withhold shares at settlement to cover the estimated payroll withholding tax obligations. During 2020, we settled 1,218,945 shares underlying RSUs, of which 276,822 shares underlying RSUs were net settled by withholding 106,459 shares. The value of the shares underlying RSUs withheld was $1.5 million, based on the closing price of our common stock on the settlement date. During 2019, we settled 574,168 shares underlying RSUs, of which 488,964 shares underlying RSUs were net settled by withholding 212,879 shares. The value of the shares underlying RSUs withheld was $6.7 million, based on the closing price of our common stock on the settlement date. The value of RSUs withheld in each period was remitted to the appropriate taxing authorities and has been reflected as a financing activity in our consolidated statements of cash flows.

Stock Options

The following is a summary of stock option activity under our 2014 EIP and Inducement Plan. The table below also includes the activity relating to options for 275,000 shares of our common stock which were issued in 2017 outside of these plans:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2019	6,934,262	$ 28.25	5.9	$ 4,103
Granted	2,641,125	12.01		
Exercised	(268,938)	14.75		
Forfeited or expired	(1,454,563)	30.17		
Balance as of December 31, 2020	7,851,886	$ 22.89	6.4	$ 26,834
Vested and expected to vest as of December 31, 2020	7,851,886	$ 22.89	6.4	$ 26,834
Exercisable as of December 31, 2020	3,747,718	$ 26.74	4.5	$ 6,214

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2020 and the exercise price of outstanding, in-the-money options. As of December 31, 2020, there was $48.8 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.6 years.

Options for 268,938, 347,716 and 1,051,180 shares of our common stock were exercised during the years ended December 31, 2020, 2019 and 2018, with an intrinsic value of $1.0 million, $3.8 million and $19.2 million, respectively. As we believe it is more likely than not that no stock option related tax benefits will be realized, we do not record any net tax benefits related to exercised options.

The fair value of each option issued was estimated at the date of grant using the Black-Scholes valuation model. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes model and resulting weighted-average grant date fair values of stock options granted during the periods indicated:

	Year ended December 31,		
	2020	2019	2018
Assumptions:			
Expected term (years)	6.0	5.9	4.6
Expected volatility	76.8%	76.1%	73.5%
Risk-free interest rate	0.8%	2.1%	2.7%
Expected dividend yield	0.0%	0.0%	0.0%
Fair Value:			
Weighted-average estimated grant date fair value per share	$ 7.96	$ 18.06	$ 22.96
Options granted	2,641,125	2,535,425	2,998,650
Total estimated grant date fair value	$ 21,023,000	$ 45,790,000	$ 68,849,000

The estimated fair value of stock options that vested in the years ended December 31, 2020, 2019 and 2018 was $29.4 million, $31.6 million and $16.2 million, respectively.

Employee Stock Purchase Plan

In May 2014, we adopted the 2014 Employee Stock Purchase Plan ("2014 ESPP"), which became effective on October 15, 2014 upon the pricing of our IPO. The 2014 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Eligible employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the common stock at (i) the beginning of a 12-month offering period, or (ii) at the end of one of the two related 6-month purchase periods. No participant in the 2014 ESPP may purchase shares of common stock valued at more than $25,000 per calendar year. The first offering under the 2014 ESPP commenced on June 1, 2016, and subsequent offerings commence on each anniversary of this date. The Company recorded $1.8 million, $1.3 million and $1.2 million of expense related to the 2014 ESPP in the years ended December 31, 2020, 2019 and 2018, respectively. A total of 282,514, 139,466 and 109,193 shares were purchased under the ESPP during the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, there was $0.6 million of unrecognized stock-based compensation expense related to the ESPP that is expected to be recognized by the end of second quarter of 2021.

The 2014 ESPP provides for annual increases in the number of shares available for issuance thereunder on the first business day of each fiscal year, beginning with 2015 and ending in 2024, equal to the lower of (i) one percent of the number of shares of our common stock outstanding as of such date, (ii) 230,769 shares of our common stock, or (iii) a lesser number of shares as determined by our board of directors. As of December 31, 2020, there were 1,586,742 shares authorized under the 2014 ESPP.

Reserved Shares

The following shares of common stock were reserved for future issuance under our equity incentive plans as of December 31, 2020:

	Total Shares Reserved
2014 Equity Incentive Plan	13,545,106
2018 Inducement Plan	2,634,836
2014 Employee Stock Purchase Plan	950,803
Total reserved shares of common stock	17,130,745

Stock-based Compensation Expense

Total stock-based compensation expense related to all stock awards was as follows:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Research and development	$ 31,527	$ 26,773	$ 16,211
General and administrative	19,824	24,923	17,606
Total stock-based compensation expense	$ 51,351	$ 51,696	$ 33,817

11. Income Taxes

Losses before provision for income taxes were as follows in each period presented:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
United States	$ (306,758)	$ (291,049)	$ (230,765)
Foreign	153	85	22
Total loss before provision for income taxes	$ (306,605)	$ (290,964)	$ (230,743)

The Company liquidated its Cayman Islands entity in 2018 and elected to treat the entity as disregarded for the fiscal year 2018. As such, the applicable 2018 losses are treated as losses in the United States.

The components of provision for (benefit from) income taxes were as follows in each period presented:

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Current provision for (benefit from) income taxes:			
Federal	$ —	$ —	$ (31)
State	2	—	(15)
Foreign	13	12	2
Total current provision for (benefit from) income taxes	$ 15	$ 12	$ (44)

A reconciliation of statutory tax rates to effective tax rates were as follows in each of the periods presented:

	Year Ended December 31,		
	2020	2019	2018
Federal income taxes at statutory rate	21.0%	21.0%	21.0%
Impact of stock compensation	(2.4%)	0.1%	—
Non-deductible executive compensation	(0.1%)	(0.7%)	(0.7%)
Capitalized research	—	—	7.8%
Other	0.3%	(0.2%)	(0.6%)
Change in valuation allowance	(18.8%)	(20.2%)	(27.5%)
Effective tax rate	0.0%	0.0%	0.0%

Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities were as follows for each of the dates presented:

	As of December 31,	
	2020	2019
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 237,010	$ 162,436
Stock-based compensation	20,672	17,573
Capitalized expenses	12,590	14,129
License fees	8,159	6,870
Operating lease liabilities	4,251	4,325
Legal fees	2,136	1,683
Tax credits	1,580	—
Other	5,360	3,329
Total deferred tax assets	291,758	210,345
Valuation allowance	(287,349)	(205,249)
Total deferred tax assets	4,409	5,096
Deferred tax liabilities:		
Operating lease assets	(3,541)	(3,921)
Other	(868)	(1,175)
Total deferred tax liabilities	(4,409)	(5,096)
Net deferred tax assets (liabilities)	$ —	$ —

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes, as well as for tax attribute carryforwards. We regularly evaluate the positive and negative evidence in determining the realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance and reported cumulative net losses since inception, we maintained a full valuation allowance on the net deferred tax assets as of December 31, 2020 and 2019. We intend to maintain a full valuation allowance on our deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. The valuation allowance increased by $82.1 million for the year ended December 31, 2020 and increased by $78.1 million for the year ended December 31, 2019.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was signed into law on March 27, 2020, providing companies with various tax relief provisions and other stimulus measures. Such measures include, but are not limited to, temporary changes regarding the prior and future utilization of net operating losses, technical corrections to prior tax legislation for tax depreciation of certain qualified improvement property, acceleration of AMT credit refunds, and changes to business interest limitations. The Consolidated Appropriations Act was also signed into law on December 27, 2020 to provide further relief measures and renew various expiring tax provisions. Additionally, the IRS issued final regulations and proposed regulations on calculating the limitation on business interest expense, the allowance for the first-year depreciation deduction under IRC Section 168(k), as amended by the Tax Cuts and Jobs Act (the "Tax Act"), for qualified property acquired and placed in service after September 27, 2017, and meals and entertainment deductions. Based on our evaluation, these regulations did not have a material impact on the income tax provision for the years ended December 31, 2020, 2019 and 2018.

Under the Tax Act, as modified by the CARES Act, federal net operating losses generated in tax years beginning on or after January 1, 2018 and in future years may be carried forward indefinitely, but the utilization of such federal net operating losses arising in taxable years beginning on or after January 1, 2021 is limited to 80% of a tax year's taxable income. The CARES Act temporarily suspends this 80% taxable income limitation, allowing a net operating loss carryforward to fully offset taxable income in tax years beginning before January 1, 2021. Not all states conform to the Tax Act or CARES Act and some states have varying conformity to the Tax Act or CARES Act.

As of December 31, 2020, we had federal and state net operating loss carryforwards for tax return purposes of $811.7 million and $988.1 million, respectively. Of the $811.7 million federal net operating loss carryforwards, $65.3 million will begin to expire in 2032, with the remaining $746.4 million being carried forward indefinitely. Of the $988.1 million state net operating loss carryforwards, $986.4 million will begin to expire in 2030, with the remaining amount not being subject to expiration under applicable state laws.

As of December 31, 2020, we had federal research & development and orphan drug tax credits of $12.9 million and $75.1 million, respectively, to offset future taxes payable. These federal credits begin to expire in 2032 and 2035, respectively, if not utilized. As of December 31, 2020, we had California research & development tax credits of $21.6 million, which do not expire, to offset future taxes payable.

Under Section 382 of the Internal Revenue Code of 1986, as amended, our ability to utilize net operating loss carryforwards or other tax attributes in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 "ownership change" occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws.

We have completed a Section 382 study of transactions in our stock through December 31, 2020. The study concluded that we have experienced ownership changes since inception and that our utilization of net operating loss carryforwards will be subject to annual limitations. However, it is not expected that the annual limitations will result in the expiration of tax attribute carryforwards prior to utilization.

The changes in the balance of gross unrecognized tax benefits, which excludes interest and penalties, for the years ended December 31, 2018, 2019 and 2020 are as follows:

	(In thousands)
Balance as of January 1, 2018	$ 30,051
Gross increases for tax positions related to current year	12,927
Gross increases for tax positions related to prior year	704
Gross decreases for tax positions related to prior year	(2,608)
Balance as of December 31, 2018	41,074
Gross increases for tax positions related to current year	22,800
Gross increases for tax positions related to prior year	22,126
Gross decreases for tax positions related to prior year	—
Balance as of December 31, 2019	86,000
Gross increases for tax positions related to current year	24,648
Gross increases for tax positions related to prior year	—
Gross decreases for tax positions related to prior year	(47)
Balance as of December 31, 2020	$ 110,601

The Company currently has a full valuation allowance against its U.S. net deferred tax assets, which would impact the timing of the effective tax rate benefit should any uncertain tax position be favorably settled in the future. Of the $110.6 million total unrecognized tax benefits as of December 31, 2020, no amount, if recognized, would affect the Company's effective tax rate for the years ended December 31, 2020 and 2019.

The Company's policy is to account for interest and penalties related to uncertain tax positions as a component of the income tax provision. The Company has not accrued interest and penalties as of December 31, 2020 and 2019 due to available tax losses.

Our significant jurisdictions are the U.S. federal jurisdiction and the California state jurisdiction. All of our tax years remain open to examination by the U.S. federal and California tax authorities. We also file in other state, local and foreign jurisdictions in which we operate, and such tax years remain open to examination.

As of December 31, 2020, we are permanently reinvested with respect to our foreign earnings, which are not material as our foreign operations are not significant.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2020. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2020 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020. The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in its report which is included in this Item 9A of this Annual Report on Form 10-K.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures and our internal controls will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. As these inherent limitations are known features of the financial reporting process, it is possible to design into the process safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2020, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, which were identified in connection with our evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that many of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation to minimize the impact to the design and operating effectiveness of our internal controls.

Report of Independent Registered Public Accounting Firm

This Annual Report on Form 10-K includes an attestation report from our independent registered public accounting firm.

Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of Atara Biotherapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Atara Biotherapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheet and related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows as of and for the year ended December 31, 2020, of the Company and our report dated March 1, 2021, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ DELOITTE & TOUCHE LLP

San Jose, California
March 1, 2021

Item 9B. Other Information

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2021 annual meeting of stockholders (the Definitive Proxy Statement), pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after December 31, 2020, and certain information to be included in the Definitive Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

We have adopted a Code of Conduct that applies to our officers, directors and employees which is available on our internet website at wwwatarabio.com. The Code of Conduct contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

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

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

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

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services

Information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the financial statements or notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	06/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	06/20/2014	
4.1	Form of Common Stock Certificate	S-1/A	333-196936	4.1	07/10/2014	
4.2	Form of 2019 Pre-Funded Warrant	8-K	001-36548	4.1	07/22/2019	
4.3	Form of May 2020 Pre-Funded Warrant	8-K	001-36548	4.1	05/28/2020	
4.4	Form of December 2020 Pre-Funded Warrant	8-K	001-36548	4.1	12/09/2020	
4.5	Description of Securities	10-K	001-36548	4.4	02/27/2020	
10.1*	Amended and Restated 2014 Equity Incentive Plan	10-Q	001-36548	10.2	08/08/2016	
10.2*	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan	S-1	333-196936	10.2	06/20/2014	
10.3*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2014 Equity Incentive Plan	10-Q	001-36548	10.1	11/07/2019	
10.4*	2014 Employee Stock Purchase Plan	S-1/A	333-196936	10.8	07/10/2014	
10.5*	Amended and Restated 2018 Inducement Plan	10-Q	001-36548	10.3	11/09/2020	
10.6*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the Inducement Plan	10-Q	001-36548	10.2	11/07/2019	
10.7*	Form of Stock Option Agreement and Stock Option Grant Notice under the Inducement Plan	10-Q	001-36548	10.3	05/08/2018	
10.8*	Forms of Inducement Grant Notice and Inducement Grant Agreement	10-Q	001-36548	10.3	08/07/2017	
10.9*	Form of Indemnification Agreement made by and between Atara Biotherapeutics, Inc. and each of its directors and executive officers	S-1	333-196936	10.9	06/20/2014	
10.10*	Form of Employment Agreement by and between Atara Biotherapeutics, Inc. and its executive officers.	10-Q	001-36548	10.4	08/01/2018	
10.11*	Form of Executive Employment Agreement	10-Q	001-36548	10.2	08/08/2019	
10.12*	Executive Employment Agreement, dated May 23, 2019, by and between Pascal Touchon and Atara Biotherapeutics, Inc.	8-K	001-36548	10.1	05/28/2019	
10.13†	Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015	S-1	333-205347	10.30	06/29/2015	
10.14†	Amendment No. 1 to the Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of August 30, 2018	10-K	001-36548	10.14	02/26/2019	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.15†	Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Council of the Queensland Institute of Medical Research, dated September 23, 2016, as amended	10-Q	001-36548	10.1	08/01/2018	
10.16†	Amended and Restated Research and Development Collaboration Agreement, by and between Atara Biotherapeutics, Inc. and the Council of the Queensland Institute of Medical Research, dated September 23, 2016, as amended	10-Q	001-36548	10.2	08/01/2018	
10.17+	Second Amended and Restated Research and Development Collaboration Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 28, 2019	10-Q	001-36548	10.3	11/07/2019	
10.18+	Second Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 28, 2019	10-Q	001-36548	10.4	11/07/2019	
10.19+	Third Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 26, 2020	10-Q	001-36548	10.1	11/09/2020	
10.20+	Third Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 26, 2020	10-Q	001-36548	10.2	11/09/2020	
10.21†	Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated August 2015, as amended	10-Q	001-36548	10.3	08/01/2018	
10.22+	Amended and Restated Amendment No. 2 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 4, 2018	10-Q	001-36548	10.5	11/07/2019	
10.23+	Amendment No. 3 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated June 28, 2019	10-Q	001-36548	10.6	11/07/2019	
10.24+	Amendment No. 4 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 4, 2019	10-K	001-36548	10.22	02/27/2020	
10.25+	Amendment No. 5 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 27, 2019	10-K	001-36548	10.23	02/27/2020	
10.26+	Commercial Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated December 24, 2019	10-K	001-36548	10.24	02/27/2020	
10.27	Office Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated as of December 9, 2015	10-K	001-36548	10.29	03/04/2016	
10.28	First Amendment to Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated October 21, 2020	10-Q	001-36548	10.4	11/09/2020	
10.29	Standard Industrial Lease by and between Thousand Oaks Industrial Portfolio, LLC and Atara Biotherapeutics, Inc. dated February 6, 2017	10-Q	001-36548	10.1	05/04/2017	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.30+	Research, Development and License Agreement, by and between Atara Biotherapeutics, Inc. and Bayer AG, dated December 4, 2020					X
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (included on signature page)					
31.1	Certification of the Chief Executive Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of the Chief Financial Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL					X

† Confidential treatment has been granted for a portion of this exhibit.

+ Portions of this exhibit have been omitted as being both (i) not material and (ii) would likely cause competitive harm if publicly disclosed.

* Indicates management contract or compensatory plan or arrangement.

(1) The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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, in the City of South San Francisco, State of California, on the 1st day of March, 2021.

Atara Biotherapeutics, Inc.

By: /s/ Pascal Touchon
Pascal Touchon
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Pascal Touchon and Utpal Koppikar, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Pascal Touchon Pascal Touchon	President, Chief Executive Officer and Director (*principal executive officer*)	March 1, 2021
/s/ Utpal Koppikar Utpal Koppikar	Chief Financial Officer (*principal financial and accounting officer*)	March 1, 2021
/s/ Ronald Renaud Ronald Renaud	Director, Chairman	March 1, 2021
/s/ Eric L. Dobmeier Eric L. Dobmeier	Director	March 1, 2021
/s/ Matthew K. Fust Matthew K. Fust	Director	March 1, 2021
/s/ Carol G. Gallagher Carol G. Gallagher, Pharm.D.	Director	March 1, 2021
/s/ William K. Heiden William K. Heiden	Director	March 1, 2021
/s/ Beth Seidenberg Beth Seidenberg, M.D.	Director	March 1, 2021
/s/ Maria Grazia Roncarolo Maria Grazia Roncarolo, M.D.	Director	March 1, 2021
/s/ Roy Baynes Roy Baynes, M.D., Ph.D.	Director	March 1, 2021

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL, AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.30

Execution Version

RESEARCH, DEVELOPMENT AND LICENSE AGREEMENT

This LICENSE AGREEMENT ("Agreement") is entered into as of December 4, 2020 (the "Effective Date") by and between:

Bayer AG ("Bayer"), a company organized under the Laws of Germany, whose office is situated at Müllerstraße 178, 13353 Berlin, Germany,

and

Atara Biotherapeutics, Inc.("Atara"), a company organized under the Laws of Delaware, whose office is situated at 611 Gateway Blvd, Suite 900, South San Francisco, CA 94080, U.S.A.

Bayer and Atara shall also each individually be referred to herein as a "Party", and shall be referred to collectively as the "Parties".

RECITALS

WHEREAS, Bayer is engaged in the development, commercialization and manufacture of pharmaceutical products;

WHEREAS, Atara owns - partly through ownership, partly through acquired license - certain patent rights, know how and other intellectual property relating to Licensed Cell Therapeutics (as hereinafter defined), and is developing the Licensed Cell Therapeutics for the treatment or prevention of cancer;

WHEREAS, Bayer desires to obtain from Atara, and Atara is willing to grant to Bayer, an exclusive license and, to the extent that it controls the intellectual property through acquired license, an exclusive sublicense under certain intellectual property rights Controlled by Atara to Develop, Commercialize and Manufacture the Licensed Cell Therapeutics in the Field in the Territory, on the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the recitals above and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

DEFINITIONS

For purposes of this Agreement, the terms defined in this section and used in this Agreement with a capital initial letter shall have the respective meanings set forth below.

1.01 ***"Acquired Affiliate", "Acquired Competing Products" and "Acquisition Date" each have the meaning as set forth in Section 15.4.1.***

1.02 ***"Agreement" has the meaning set forth in the introductory paragraphs of this Agreement.***

1.03 ***"Affiliate" means any business entity controlled by, controlling or under common control with a Party at the Effective Date or at any time during the term of this Agreement and as long as such control remains. For the purpose of this definition, a business entity shall be deemed to "control" another business entity if it:***

(i) owns directly or indirectly more than fifty percent (50%) of the outstanding voting securities, capital stock or other comparable equity or ownership interest of such business entity having the power to vote on or direct the affairs of such business entity, as applicable (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), or

(ii) possesses, directly or indirectly, the power to direct or cause the direction of the policies and management of such business entity, as applicable, whether by the ownership of stock, by contract or otherwise.

1.04 ***"Alliance Manager" has the meaning set forth in Section 3.6.2 below.***

1.05 ***"Anti-Corruption Laws" means the United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and any other Laws of a similar nature for the prevention of fraud, corruption, racketeering, money laundering and terrorism, in each case as they may be amended from time to time.***

1.06 ***"ATA2271" means the autologous CAR-T product comprising an m912 scFv binder, a 1XX signaling domain and a co-expressed PD1-DNR element that is the subject of the Phase 1 Clinical Trial having ClinicalTrials.gov identifier NCT04577326.***

1.07 ***"ATA2271 Phase 1 Clinical Trial" means the Phase 1, first in human clinical research program relating to ATA2271 for the treatment of mesothelioma (ClinicalTrials.gov identifier NCT04577326) in the manner outlined within the ATA2271 Plan.***

1.08 ***"ATA2271 Plan" means the plan attached to this Agreement as Exhibit 1.8, which sets forth the activities for the development of ATA2271, including the ATA2271 Phase 1 Clinical Trial [[***]], as such plan may be amended by the JSC in accordance with Section 3.6.3.2(vi).***

1.09 ***"ATA3271" means Atara's allogeneic version of the ATA2271 CAR-T product based on Atara's proprietary technology entailing the use of T cells activated against EBV.***

1.10 ***"Atara" has the meaning set forth in the introductory paragraphs of this Agreement.***

1.11 ***"Atara Indemnified Parties" has the meaning set forth in Section 16.1 below.***

1.12 ***"Atara Cell Therapeutic" means ATA2271, ATA3271 [[***]].***

1.13 ***"Atara FTE Rate" means the annual rate of [[***]] per FTE employed or contracted by Atara or any of its Affiliates based upon the fully burdened cost of such personnel, such amount to be adjusted as of [[***]] of each following Calendar Year, by the percentage increase or decrease, if any, in the Consumer Price Index (Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics, or its successor equivalent index) through [[***]] of the prior year.***

1.14 ***"Atara Results" means any Collaboration Results solely made by Atara's employees, agents, representatives or contractors, in each case in the course of or as a result of the performance of the Collaboration Activities. For clarity, "Atara Results" includes any and all data generated by MSK for ATA2271.***

1.15 ***"Bayer" has the meaning set forth in the introductory paragraphs of this Agreement.***

1.16 ***"Bayer Background Improvement" means any Results that are solely related to the Bayer Background Technology and not specific to the Collaboration Activities.***

1.17 ***"Bayer Background Technology" means any Know How, Patent Right or other intellectual property right that is both (a) Controlled by Bayer (i) as of the Effective Date or (ii) during the Collaboration Term and generated outside the performance of the Collaboration Activities; and (b) is used by Bayer, or provided by Bayer to Atara for use, in the performance of the Collaboration Activities.***

1.18 ***"Bayer FTE Rate" means the annual rate of [[***]] per FTE employed or contracted by Bayer or any of its Affiliates based upon the fully burdened cost of such personnel, such amount to be adjusted as of [[***]] of each following Calendar Year, by the percentage increase or decrease, if any, in the price index for German F&E personnel within the pharmaceutical industry, as published in the annual publication "Chemiewirtschaft in Zahlen" edited by Verband der Chemischen Industrie e.V. of the previous year.***

1.19 ***"Bayer Improvement IP" has the meaning set forth in Section 11.2.2.4.***

1.20 ***"Bayer Indemnified Parties" has the meaning set forth in Section 16.2 below.***

1.21 ***"Bayer Marks" means any proprietary name, logotype, trade dress or other Marks of Bayer or any of its Affiliates and any Product Marks (including any Mark that includes the name "Bayer" or the "Bayer Cross").***

1.22 ***"Bayer Party" means Bayer, its Sublicensee(s) and any of Bayer's or its Sublicensee's Affiliates.***

1.23 ***"Bayer Results" means any Collaboration Results solely made by Bayer's employees, agents, representatives or contractors.***

1.24 ***"Biosimilar Product" means, on a country-by-country basis, with respect to a Licensed Product being sold in any country, a product that (a) contains the same or substantially the same active cellular agent irrespective of its form as such Licensed Product regardless of the***

dosage and formulation of such product; (b) obtained Regulatory Approval by means of an Abbreviated New Drug Application filing or another procedure for establishing equivalence to such Licensed Product that does not require clinical testing (other than a bioequivalence or substantially similar study); and (c) is legally marketed in such country by an entity other than a Bayer Party.

1.25 ***"BioVec" means BioVec Pharma, Inc., with a place of business located at 1202 rue du Capitaine Bernier, Quebec, QC, Canada.***

1.26 ***"BioVec Upstream License" means the License Agreement between Atara and BioVec Pharma, Inc., dated October 7, 2020.***

1.27 ***"BLA" means with respect to a Licensed Product, a filing serving to apply for Regulatory Approval including, in the United States, a Biologics License Application (as defined in the FDC Act and the regulations promulgated thereunder (21 CFR 600 et seq)), in the European Union, a Marketing Approval Application (MAA), or, in any other jurisdiction, a comparable filing, and, in each case, any amendments and supplements thereto.***

1.28 ***"Business Day" means a day other than a Saturday, Sunday or any day on which commercial banks located in (i) San Francisco, California, U.S.A., (ii) Berlin, Germany or (iii) Leverkusen, Germany are authorized or obligated by law to be closed.***

1.29 ***"Calendar Year" means a period of twelve (12) consecutive months corresponding to the calendar year commencing on the first day of January and ending on the last day of December.***

1.30 ***"CAR" means [[***]].***

1.31 ***"CAR-T(s)" means [[***]].***

1.32 ***"cGCP" means regulations and published guidelines related to current good clinical practices that relate to the conduct of clinical studies in humans including the regulations set forth in 21 CFR 50, 54, 56, 312 and 314 promulgated by the FDA, the ICH Harmonised Tripartite Guideline for Good Clinical Practice and similar standards, guidelines and regulations promulgated or otherwise required by other Regulatory Authorities, in each case, as they may be amended from time to time.***

1.33 ***"cGLP" means regulations and published guidelines related to current good laboratory practices that relate to the conduct of preclinical studies in animals including the regulations set forth in 21 CFR 58 promulgated by the FDA and similar standards, guidelines and regulations promulgated or otherwise required by other Regulatory Authorities, in each case, as they may be amended from time to time.***

1.34 ***"cGMP" means regulations and published guidelines related to current good manufacturing practices that relate to the testing, manufacturing, processing, packaging, holding or distribution of drug or biologic drug substances and finished drugs or biologics including the regulations set forth in 21 CFR 210 and 211 promulgated by the FDA and***

similar standards, guidelines and regulations promulgated or otherwise required by other Regulatory Authorities, in each case, as they may be amended from time to time.

1.35 ***"Change of Control" means with respect to a Party:***

(i) that a majority of the outstanding voting securities of such Party become beneficially owned directly or indirectly by any Third Party (or group of Third Parties acting in concert) that did not own a majority of the voting securities of such Party as of the Effective Date;

(ii) that the possession of the power to direct or cause the direction of the management and policies of such Party, whether through ownership of the outstanding voting securities or by contract or otherwise, becomes vested in one or more individuals or entities that did not possess such power as of the Effective Date;

(iii) that such Party consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such Party, in either event pursuant to a transaction in which more than fifty percent (50%) of the total voting power of the securities outstanding of the surviving entity normally entitled to vote in elections of directors is not held by the individuals or entities holding at least fifty percent (50%) of the outstanding securities of such entity preceding such consolidation or merger; or

(iv) such Party conveys, transfers or leases all or substantially all of the assets of such Party to which the subject matter of this Agreement relates to any Third Party.

1.36 ***"Clinical Trials" means Phase 1 Clinical Trials, Phase 2 Clinical Trials and / or Phase 3 Clinical Trials.***

1.37 ***"CMC Activities" means the activities specified in Section 3.1.2.***

1.38 ***"CMC Plan" means the plan attached to this Agreement as Exhibit 1.38 [[***]] as such plan may be amended by both Parties in accordance with Section 3.5.***

1.39 ***"Collaboration Activities" means each of (a) the Research Activities and (b) the CMC Activities.***

1.40 ***"Collaboration Plan(s)" means the Research Plan and the CMC Plan.***

1.41 ***"Collaboration Results" means any and all Results except for the Bayer Background Improvements.***

1.42 ***"Collaboration Term" means, with respect to each of (a) the Research Activities and (b) the CMC Activities, the period for the performance of such Collaboration Activities, as set forth in the relevant Collaboration Plan.***

1.43 ***"Combination Licensed Product" means a product for use in the Field sold in a single stock keeping unit (SKU) for a single selling price, wherein such product utilizes, contains, incorporates or is made through the use of one or more Licensed Cell Therapeutic(s) or Licensed Product(s) in combination with one or more other products, components or ingredients including compounds, that are not Licensed Cell Therapeutics or Licensed Products, and are not required for the independent function of the included Licensed Cell Therapeutic(s) or Licensed Product(s). For clarity, a Combination Licensed Product shall constitute a Licensed Product, when that defined term is used herein, provided that [[***]].***

1.44 ***"Commercialize" or "Commercialization" means all activities undertaken relating to use for commercial purposes, [[***]].***

1.45 ***"Commercially Reasonable Efforts" means [[***]].***

1.46 ***"Company Core Data Sheet" means the global reference labeling document used to direct the content of country-specific labeling for Licensed Products.***

1.47 ***"Competing Product" means [[***]].***

1.48 ***"Complete Invention Disclosure" means a description of the invention which shall include, in reasonable detail, a description of (i) database searches on state of the art undertaken; (ii) relevant prior art references found including an assessment of their relevance to the invention, (iii) the technical problem underlying the invention, (iv) the solution to this problem, (v) the technical, economic and commercial advantages of the solution particularly as compared to prior solutions to, and / or attempts to solve the problem (vi) the names and private addresses of the inventors, (vii) the individual contribution of each inventor to the invention, (viii) examples, all materials and methods used in connection with performing the invention, (ix) any and all sources of funding for the work done on the invention, (x) the date, if any, the invention was first publicly disclosed, (xi) any publications discussing or describing the invention; and (xi) any encumbrance related to the invention.***

1.49 ***"Confidential Information" has the meaning set forth in Section 12.1.1 below.***

1.50 ***"Control" means, with respect to any Patent Rights or Know How and subject to the second sentence of this Section 1.50, the ownership or possession by a Party of the right, power and authority to license or sublicense such Patent Rights or Know How, as applicable, on the terms and conditions set forth in this Agreement, without violating the terms of any then-existing agreement with any Third Party. In the event a Party enters into a transaction or series of transactions with a Third Party acquiror that constitutes a Change of Control of such Party, in no event shall any Know How or Patent Rights that***

1) were immediately prior to the consummation of such Change of Control controlled by the Third Party acquiror or its affiliates, or

2) [[***]],

be deemed "Controlled" by the acquired Party (or such Party's other Affiliates) for purposes of this Section 1.50 or otherwise be included in any of the licenses or

covenants granted or made under this Agreement by the acquired Party (or such Party's other Affiliates) ; [[***]].

1.51 ***"Derivative Cell Therapeutic" means any cell therapeutic [[***]].***

1.52 ***"Develop" or "Development" means to engage in research and development activities (including preclinical studies, translational studies, Clinical Trials, CMC development and regulatory activities).***

1.53 ***"Disclosing Party" has the meaning set forth in Section 12.1.1 below.***

1.54 ***"EBV" means Epstein-Barr Virus.***

1.55 ***"Effective Date" has the meaning set forth in the introductory paragraphs of this Agreement.***

1.56 ***"EMA" means the European Medicines Agency or any successor agency thereto.***

1.57 ***"Exclusive Technology" means all Licensed Technology other than the Non-Exclusive Technology.***

1.58 ***"Executive Sponsor" means, (a) with respect to Atara, [[***]], and (b) with respect to Bayer,[[***]], in each case (a) and (b), or such other person designated by one Party to the other Party in writing from time to time.***

1.59 ***"Existing Agreement(s)" means those agreements listed in Exhibit 1.59 hereto.***

1.60 ***"Exploit" or "Exploitation" means to use, Develop, have Developed, Commercialize, have Commercialized, Manufacture and have Manufactured.***

1.61 ***"FDA" means the United States Food and Drug Administration or any successor agency thereto.***

1.62 ***"FDC Act" means the United States Food, Drug and Cosmetic Act, as amended from time to time, and regulations promulgated thereunder.***

1.63 ***"Field" means[[***]].***

1.64 ***"Field Infringement" has the meaning set forth in Section 11.7.1.***

1.65 ***"Final Bayer Offer" has the meaning as set forth in Section 2.5.2.6.***

1.66 ***"Final Third Party Offer Notice" has the meaning as set forth in Section 2.5.2.5.***

1.67 ***"First Commercial Sale" means, on a country-by-country basis, the first invoiced sale of Licensed Product by a Bayer Party to a Third Party after grant of a Regulatory Approval in the applicable country or jurisdiction[[***]].***

1.68 ***"Force Majeure" has the meaning as set forth in Section 19.1 below.***

1.69 ***"FTE" means, with respect to a Party, the equivalent of a full-time employee employed or contracted by such Party to the performance of research, development, or other activities under this Agreement based upon a total of [[***]] per year of research, development, or other work. For clarity, the Parties intend the FTE to be a unit of measurement used to calculate the amount of time dedicated to the performance of this Agreement by a Party. One FTE may constitute work performed by an individual whose time is dedicated solely to this Agreement (but, for clarity, under no circumstances may more than one (1) FTE per year be allocated to one and the same individual) or may comprise the efforts of several individuals, each of whom dedicates only part of his or her time to work under this Agreement.***

1.70 ***"Improvements" mean any invention, discovery, development or modification, whether or not patentable, that (a) is made with respect to a Licensed Cell Therapeutic or Licensed Product, or the Development, Commercialization or Manufacturing thereof, (b) is conceived, reduced to practice, discovered, or developed at any time during the term of this Agreement, and (c) is reasonably useful for the Exploitation of such Licensed Cell Therapeutic or Licensed Product, including any enhancement in the efficiency, operation, manufacture, cost of manufacture, ingredients, preparation, presentation, formulation, means of delivery or dosage, use, or methods of use or packaging of such Licensed Cell Therapeutic or Licensed Product, any discovery or development of any new or expanded indications for such Licensed Cell Therapeutic or Licensed Product, any discovery or development that improves the stability, safety or efficacy of such Licensed Cell Therapeutic or Licensed Product or would, if Commercialized, replace or displace such Licensed Cell Therapeutic or Licensed Product for the indication for which such Licensed Cell Therapeutic or Licensed Product has received Regulatory Approval or for which Bayer is seeking Marketing Approval in the Field.***

1.71 ***"IND" means a filing with a Regulatory Authority that must be made prior to commencing clinical testing in humans including, (a) in the United States, an Investigational New Drug application (as defined in the FDC Act and the regulations promulgated thereunder (21 CFR 312.1 et seq)), (b) in the European Union, a Clinical Trial Application (CTA), or (c) in any other jurisdiction, a comparable filing and, in each case (a) through (c), any amendments and supplements thereto.***

1.72 ***"IND Readiness" means [[***]].***

1.73 ***"Indemnified Party" has the meaning set forth in Section 16.3.1 below.***

1.74 ***"Indemnifying Party" has the meaning set forth in Section 16.3.1 below.***

1.75 ***"Invention" has the meaning set forth in Section 11.3 below.***

1.76 ***"Joint Invention" means any Invention within the Collaboration Results made jointly by one or more employees, officers, directors, consultants or directors of Atara and by one or more employees, officers, directors, consultants or directors of a Bayer Party.***

1.77 ***"Joint Results Patent" means any Patent Right filed, sought or obtained covering Joint Inventions.***

1.78 ***"Joint Results" means any Collaboration Results generated jointly by one or more employees, officers, directors, consultants or directors of Atara and by one or more employees, officers, directors, consultants or directors of a Bayer Party.***

1.79 ***"Joint Steering Committee" or "JSC" has the meaning set forth in Section 3.6.3 below.***

1.80 ***"Know How" means all intellectual property (other than Patent Rights), including all proprietary and confidential commercial, technical, scientific and other information, inventions (whether patentable or not), trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know how, including study designs and protocols), in all cases whether in written, electronic or any other tangible or non-tangible form, including information related to materials, samples, assays, compounds, compositions or formulations. [[***]].***

1.81 ***"Knowledge" means, with respect to a Party, [[***]].***

1.82 ***"Laws" means all applicable laws (including Anti-Corruption Laws), statutes, rules, regulations (including cGCP, cGLP and cGMP), orders, judgments and / or ordinances of any Regulatory Authority, governmental authority or court or any subpoena of a competent court having effect from time to time in the Territory.***

1.83 ***"Licensed Cell Therapeutic" means any Atara Cell Therapeutic or Derivative Cell Therapeutic.***

1.84 ***"Licensed Know How" means any Know How relating to Atara Cell Therapeutic(s) and / or Licensed Product(s) comprising an Atara Cell Therapeutic [[***]] for the development, manufacture and / or commercialization of Licensed Products comprising an Atara Cell Therapeutic, which are owned by or otherwise under the Control of Atara as of the Effective Date or at any time during the term of this Agreement until (i) [[***]] and (ii) [[***]]. Licensed Know How includes the Know How listed in Exhibit 1.84, but excludes (a) Know How only Controlled through the MOFFITT Upstream Licenses and (b) New Technology.***

1.85 ***"Licensed Patent Rights" means any of the following:***

(i) the Patent Rights listed in Exhibit 1.85 hereto;

(ii) any other Patent Rights Controlled by Atara or any of its Affiliates as of the Effective Date or at any time during the term of this Agreement, that cover the Atara Cell Therapeutic(s) and / or Licensed Product(s) comprising an Atara Cell Therapeutic, including the development, manufacture and / or commercialization thereof, but excluding (a) Patent Rights only Controlled through the MOFFITT Upstream Licenses and (b) Patent Rights constituting New Technology; and

(iii) any Patent Right Controlled by Atara or any of its Affiliates belonging to the same patent family of the Patent Rights included in clauses (i) and (ii), whether existing at the Effective Date or thereafter, including any Patent Rights filed from or claiming the same priority of the Patent Rights included in clauses (i) and (ii) in any country or region of the Territory.

1.86 ***"Licensed Product" means any product in the Field in the Territory comprising a Licensed Cell Therapeutic (alone or with other ingredients) and covered by at least one (1) Valid, Practiced Claim of any Licensed Patents or directly generated with the use of Licensed Know How.***

One Licensed Product, as opposed to another Licensed Product, shall be defined as follows:

(i) any (a) modifications or improvements in the [[***]], and / or (b) modifications or improvements of [[***]] shall be deemed only variations of the same Licensed Product [[***]]; whereas

(ii) any Licensed Product containing a cell that has been reengineered to [[***]], [[***]] shall be deemed another Licensed Product [[***]].

1.87 ***"Licensed Technology" means the Licensed Patent Rights and Licensed Know How.***

1.88 ***"Losses" has the meaning set forth in Section 16.1 below.***

1.89 ***"Major Markets" means [[***]].***

1.90 ***"Mandatory Public Communication" means a Public Communication which is required by Laws, Securities Exchange Rules or a Regulatory Authority's valid request.***

1.91 ***"Manufacture" and "Manufacturing" means all operations required to manufacture, test, release, handle, package, store and destroy a product, including formulation and process development, all subsequent packaging and labeling activities, and quality control and other testing.***

1.92 ***"Mark" means any word, name, symbol, color, designation or device or any combination thereof for use in the course of trade, including all trademarks, service marks, brand mark, logos, slogans, trade dress, logos, slogans, designs, brand names, trade names, business symbols, domain names and all other indicia of origin, together with all translations, adaptations, derivations, and combinations thereof, and all registrations, applications for registration thereof and social media handles associated therewith, together with any extensions and renewals thereof and all goodwill associated therewith.***

1.93 ***"Materials" has the meaning set forth in Section 2.6.1 below.***

1.94 ***"Mesothelin" means [[***]].***

1.95 ***"MOFFITT" means H.Lee Moffitt Cancer Center and Research Institute, Inc. with a place of business located at 12902 Magnolia Drive, Tampa, Florida 33612, U.S.A.***

1.96 ***"MOFFITT Option Period" has the meaning set forth in Section 2.5.1.***

1.97 ***"MOFFITT Upstream Licenses" means the licenses granted by MOFFITT to Atara as of the Effective Date under the agreements listed in Exhibit 1.97, as may be amended from time to time. [[***]].***

1.98 ***"MSK" means Memorial Sloan Kettering Cancer Center with a place of business located at 1275 York Avenue, New York, New York 10065, U.S.A.***

1.99 ***"MSK CAR-T License" means the agreement specified under (i) of Exhibit 1.102 ("MSK Upstream Licenses).***

1.100 ***"MSK MSLN License" means the agreement specified under (iv) of Exhibit 1.102 ("MSK Upstream Licenses"), as amended.***

1.101 ***"MSK PD1-DNR License" means the agreement specified under (v) of Exhibit 1.102 ("MSK Upstream Licenses").***

1.102 ***"MSK Upstream Licenses" means the licenses granted by MSK to Atara under the agreements listed in Exhibit 1.102, as may be amended from time to time. [[***]].***

1.103 ***"Net Sales" shall mean the gross amount [[***]] for sales of a Licensed Product (or Combination Licensed Product) to Third Parties, less the following deductions:***

(i) Taxes (including sales, value-added, consumption and similar taxes), duties and other governmental charges actually incurred paid or collected and remitted to the relevant tax or other authority for the sale, export, import, transfer or use of Licensed Products;

(ii) credits, reserves or allowances granted for (a) damaged, outdated, returned, rejected, withdrawn or recalled Licensed Product, (b) wastage replacement and short-shipments; (c) billing errors and (d) indigent patient and similar programs (e.g., price capitation);

(iii) cash, trade, volume, and prompt payment discounts actually granted and deducted solely on account of sales of Licensed Products (or Combination Products);

(iv) rebates actually paid to individual or group purchasers of Licensed Products that are solely on account of the purchase of such Licensed Products;

(v) rebates, fees, discounts or other charges paid as required by government or public healthcare legislation granted to governmental healthcare organizations, purchasing groups, wholesalers, distributors, selling agents (excluding any sales representatives of a selling party), group purchasing organizations, Third Party payors, other contractees and managed care entities;

(vi) retroactive price reductions actually granted to the Third Party applicable to sales of the Licensed Product;

(vii) [[***]] percent [[***]] lump sum of the gross amount invoiced to cover transportation, freight, distribution and shipping (including insurance), packaging and handling expenses; and

(viii) [[***]] percent [[***]] lump sum of the gross amount invoiced to cover uncollectible amounts accrued, with respect to the sale of Licensed Products.

Gross sales of Licensed Products shall be deemed to have been made on [[***]] in accordance with their standard accounting procedures. For clarity, Net Sales shall include [[***]].

All deductions from gross sales except those defined above as [[***]] may be made on an accrual basis. For the avoidance of doubt, any provision release after the end of the Royalty Term shall be royalty bearing.

For the purpose of calculating Net Sales, the Parties recognize that: (a) customers may include [[***]]; and (b) in such cases, [[***]] can be deducted from the total gross amount invoiced in order to calculate Net Sales.

In the event that a Licensed Product is sold in the form of a Combination Licensed Product, then, for the purpose of calculating royalties due, Net Sales will be adjusted by multiplying by the fraction A/(A+B) where A is the gross per unit invoice price of the Licensed Product, if sold separately, and B is the gross per unit invoice price of any other active ingredient(s) in the combination, if sold separately.

If, on a country-by-country basis, the other active ingredient(s) in the combination are not sold separately in that country, Net Sales will be adjusted by multiplying by the fraction A/C where A is the gross per unit invoice price of the Licensed Product, if sold separately, and C is the gross per unit invoice price of the Combination Licensed Product. In each case, the gross per unit invoice price shall be those applicable during the relevant Quarter or, if sales of both the Licensed Product and the other product(s) did not occur in such Quarter, then in the most recent Quarter in which sales of both occurred. If, on a country-by-country basis, neither the Licensed Product nor the other active ingredient(s) of the Combination Licensed Product are sold separately in such country, then the fraction by which the Net Sales value shall be multiplied shall be determined between the Parties in good faith.

1.104 ***"New Technology" means Patent Rights and Know How that are [[***]] for the Exploitation of the Licensed Cell Therapeutics or the Licensed Products and come into Atara's Control through upstream licenses agreed after the Effective Date with licensors other than MSK and NIH.***

1.105 ***"New Technology Offer" has the meaning set forth in Section 2.3.***

1.106 ***"NIH" means the National Institutes of Health, which is the agency of the United States of America (U.S.A.) Public Health Service (PHS) within the Department of Health and Human Services (HHS) of the U.S.A.***

1.107 ***"NIH Benchmarks" has the meaning set forth in Section 4.4.2.***

1.108 ***"NIH Upstream License" means the licenses granted by NIH to Atara under the patent license agreement effective December 18, 2018, as amended by Amendment No. 1 effective December 1, 2020, and as may be further amended from time to time. For clarity, Atara may not agree to an amendment of the NIH Upstream License other than in accordance with Atara's covenants and other obligations under this Agreement (subject in all cases to NIH's unilateral right to amend pursuant to the terms of the NIH Upstream License).***

1.109 ***"Non-Exclusive Technology" means (a) those Patent Rights and Know How constituting the Licensed Patent Rights and Licensed Know How in-licensed by Atara pursuant to the [[***]]; for clarity, Non-Exclusive Technology excludes Collaboration Results (as such term is defined in [[***]]) relating to manufacturing processes, methods or assays specific to Licensed Products, which are exclusively licensed by [[***]] to Atara; and (b) those Patent Rights and Know How constituting the Licensed Patent Rights and Licensed Know How in-licensed by Atara pursuant to [[***]] for which, as of the Effective Date, [[***]] has granted to Atara a non-exclusive, sublicensable license.***

1.110 ***"Objection Notice" has the meaning as set forth in Section 2.5.2.5.***

1.111 ***"Other CAR-T" means [[***]].***

1.112 ***"Party" or "Parties" has the meaning set forth in the introductory paragraphs of this Agreement.***

1.113 ***"Patent Challenge" has the meaning set forth in Section 18.2.3.***

1.114 ***"Patent Rights" mean:***

(i) all national, regional and international patents, patent applications, utility models, design patents and design rights filed in any country of the world including provisional patent applications;

(ii) all patents, patent applications, utility models, design patents and design rights filed either from such patents, patent applications, utility models, design patents, design rights or provisional patent applications or claiming priority from either of these, including any continuation, continuation-in part, division, provisional, converted provisional and continued prosecution applications, or any substitute application;

(iii) any patent issued with respect to or in the future issued from any such patent applications;

(iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including reissues, re-examinations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents, patent applications, utility models, design patents and design rights; and

(v) any foreign counterparts of the foregoing.

1.115 ***"Payment Date" has the meaning set forth in Section 9.6.2 below.***

1.116 ***"Phase 1 Clinical Trial" means a human clinical trial of a Licensed Cell Therapeutic, the principal purpose of which is to determine initial tolerance or safety of such Licensed Cell Therapeutic in the target patient population, including, in the United States, a human clinical trial as described in 21 CFR 312.21(a), or, in a country other than the United States, a similar clinical study prescribed by the applicable Regulatory Authority.***

1.117 ***"Phase 2 Clinical Trial" means a human clinical trial of a Licensed Cell Therapeutic, the principal purpose of which is to evaluate the effectiveness of such Licensed Cell Therapeutic in the target patient population, including, in the United States, a human clinical trial as described in 21 CFR 312.21(b), or, in a country other than the United States, a similar clinical study prescribed by the applicable Regulatory Authority.***

1.118 ***"Phase 3 Clinical Trial" means a human clinical trial of a Licensed Cell Therapeutic, on a sufficient number of subjects that is designed to form the basis for the BLA for Regulatory Approval of the Licensed Cell Therapeutic including, in the United States, a human clinical trial as described in 21 CFR 312.21(c), or, in a country other than the United States, a similar clinical trial prescribed by the applicable Regulatory Authority, but not under accelerated approval regulations in the United States as described in 21 CFR 601, subpart E, or similar conditions of an applicable Regulatory Authority in a country other than the United States.***

1.119 ***"Preliminary Bayer Offer", "Preliminary Third Party Offer" and "Preliminary Third Party Offer Period" each have the meaning as set forth in Section 2.5.2.3.***

1.120 ***"Pricing Approval" means all applicable governmental pricing and reimbursement approvals required from the relevant Regulatory Authority to market and sell and / or obtain reimbursement for, the Licensed Product in a particular country or jurisdiction.***

1.121 ***"Product Marks " means any Mark Controlled by a Bayer Party and used in connection with the Development, Commercialization or Manufacture of the Licensed Product; for the avoidance of doubt, Product Marks do not include the Bayer Marks.***

1.122 ***"Program Transfer" has the meaning set forth in Section 18.3.4.2.***

1.123 ***"Public Communication(s)" means any communication by a Party, whether made in writing, orally or in any other form, (i) which is directed to the general public, media, analysts, investors, attendees of industry conferences or financial analyst calls or similar audiences (including press releases, statements in corporate material, on internet sites or in investor relations material and any written or oral response to media inquiries or to questions in***

shareholder meetings or financial analyst calls), (ii) which refers to the transaction contemplated under this Agreement (including signing of this Agreement, reach of milestones, outcome of clinical trials, Regulatory Approval and / or launch of a Licensed Product, sales figures and development of the relevant markets, but excluding, for the sake of clarity, promotional claims regarding any Licensed Cell Therapeutic and / or Licensed Product), and (iii) which does not qualify as Scientific Communication.

1.124 ***"Quarter" means each period of three (3) months ending on March 31, June 30, September 30, or December 31, and "Quarterly" shall be construed accordingly.***

1.125 ***"Receiving Party" has the meaning set forth in Section 12.1.1 below.***

1.126 ***"Regulatory Approval" means any approval, license, registration or authorization required from the relevant Regulatory Authority to market and sell the Licensed Product in a particular country or jurisdiction; for the avoidance of doubt, Regulatory Approval does not include any Pricing Approvals.***

1.127 ***"Regulatory Authority" means the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.***

1.128 ***"Regulatory Documentation " means all applications, registrations, licenses, authorizations and approvals, all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests relating to the Licensed Product, and all data included in the foregoing, including all INDs, BLAs, Regulatory Approvals, regulatory drug lists, adverse events files and complaints files.***

1.129 ***"Research Activities" has the meaning set forth in Section 3.1.1.***

1.130 ***"Research Plan" means the plan attached to this Agreement as Exhibit 1.130, [[***]], as such plan may be amended by both Parties in accordance with Section 3.5.***

1.131 ***"Results" means any Know How and related Patent Rights that are generated in the course of or as a result of the performance of the Collaboration Activities; for clarity, Results include all Collaboration Results and Bayer Background Improvements.***

1.132 ***"Royalty Term" means, on a country-by-country basis and Licensed Product-by-Licensed Product basis, the period commencing with the First Commercial Sale of such Licensed Product in the relevant country, and ending upon the later of:***

(i) twelve (12) years from the First Commercial Sale of such Licensed Product in such country; or

(ii) expiration or termination of the last to expire Valid, Practiced Claim of a Licensed Patent covering such Licensed Product in such country that claims the [[***]] of such Licensed Product.

1.133 ***"Scientific Communication" means any communication by a Party (including documents, posters, manuscripts and abstracts, and including, with respect to Atara, any communication by MSK relating to ATA2271), whether made in writing, orally or in any other form, (i) which is directed to the general public, the scientific community, physicians, attendees of industry conferences and / or similar audiences, (ii) which is of a purely scientific or medical nature and does not qualify as promotional material under Laws, and (iii) which includes any data or results of any clinical trial or any other information regarding or related to the Licensed Cell Therapeutic and / or Licensed Product.***

1.134 ***"Securities Exchange Rules" means the applicable rules or regulations of a securities exchange or listing entity on which its publicly-traded securities are listed.***

1.135 ***"Sublicensee" means a Third Party to which Atara and/or Bayer has granted a sublicense in accordance with Section 2.1 and/or Section 2.2 of this Agreement, in each case, as the context may require.***

1.136 ***"Sublicense Income" means [[***]] received by Bayer or Bayer Affiliates from Sublicensees (other than Bayer Affiliates) as license fee for the right to Develop and / or Commercialize any [[***]].***

1.137 ***"Systemic Product" has the meaning set forth in Section 9.4.1.***

1.138 ***"Terminated Product" has the meaning set forth in Section 18.3.4.2(v).***

1.139 ***"Territory" means all countries of the world.***

1.140 ***"Third Party" means any entity or person other than a Bayer Party or Atara or its Affiliates.***

1.141 ***"Tumor Type", as opposed to another Tumor Type, shall be [[***]].***

1.142 ***"Upstream Licensors" means, with respect to (a) the MSK Upstream Licenses, MSK, (b), the NIH Upstream License, NIH, and (c) the BioVec Upstream License, BioVec.***

1.143 ***"U.S. Bankruptcy Code" has the meaning set forth in Section 18.5.1 below.***

1.144 ***"Valid, Practiced Claim" means, with respect to a Licensed Product in a particular country:***

(i) a claim of an issued Patent Right covering [[***]] that would be infringed but for the licenses granted in this Agreement and that has not (A) expired or been cancelled, (B) been declared invalid or unenforceable by a decision of a court, patent office, administrative agency, or other appropriate body of competent jurisdiction, from which no appeal is or can be taken, (C) been admitted to be invalid or unenforceable through reexamination, reissue, disclaimer or otherwise, or (D) irretrievably lapsed or been abandoned, revoked or disclaimed; provided that

(ii) solely with respect to Licensed Patent Rights within the MSK Upstream License, "Valid, Practiced Claim" also includes a claim of a pending patent application constituting a Licensed Patent Right that was filed and is being prosecuted in good faith, covering [[***]] that would, if a patent containing such claim issues, be infringed but for the licenses granted in this Agreement and that has not been (A) pending for more than [[***]] years, (B) abandoned or (C) finally disallowed without the possibility of appeal or re-filing of the application; provided, however, that in the case of (ii)(A), if, thereafter, a patent containing such claim issues, such claim shall thereafter be considered a Valid, Practiced Claim in accordance with subclause (i) above.

1.145 ***"Voluntary Public Communication" means a Public Communication which is not required by Laws, Securities Exchange Rules or a Regulatory Authority's valid request.***

1.146 ***Additional Definitions: The following table identifies the location of definitions set forth in various Sections of this Agreement:***

Defined Term	Section Reference
"Acquiror Group"	Section 15.4.5
"Acquisition Notice Period"	Section 15.4.1
"Alliance Sponsor"	Section 3.6.1
"Bayer Supplier Code of Conduct"	Section 3.3.6
"Cessation Notice"	Section 11.6.2
"Co-Chair"	Section 3.6.3.1
"Commercialization Plan"	Section 6.1.4
"Employee Data"	Section 17.4.1.3
"Human Data"	Section 17.4.1.4
"Human Samples"	Section 17.4.1.4
"JSC Charter"	Section 3.6.3.2
"Overpayment Amount"	Section 10.2.9
"Patent Matters"	Section 20.4
"Prosecuting Party"	Section 11.7.2.1

"Rules"	Section 20.2
"Upfront License Payment"	Section 9.1
"VAT"	Section 9.7.1

LICENSE GRANT, TECHNOLOGY TRANSFER

1.147 ***License Grants by Atara.***

Subject to the terms of this Agreement, Atara hereby grants to Bayer and Bayer's Affiliates

(a) a royalty- and milestone- bearing license - with the right to grant sublicenses, including the right to grant further sublicenses through multiple tiers of sublicensees pursuant to Section 2.4 below - under the Licensed Technology to Exploit Licensed Cell Therapeutics and Licensed Products in the Field in the Territory. The license granted to Bayer under this Section 2.1.1 shall be exclusive (even as to Atara and its Affiliates, except to the extent necessary or reasonably useful for Atara and its Affiliates to perform its and their obligations under this Agreement) with respect to the Exclusive Technology and non-exclusive with respect to the Non-Exclusive Technology; and

(b) a royalty-free, fully paid-up, irrevocable, perpetual, non-sublicensable, non-exclusive license under the Licensed Know How owned solely by Atara, solely for Bayer's and Bayer's Affiliates internal research purposes.

(c) Existing Agreements. Notwithstanding anything to the contrary in this Agreement, [[***]].

1.148 ***License Grant by Bayer.***

Subject to the terms of this Agreement, Bayer hereby grants to Atara and Atara's Affiliates

(a) a non-exclusive, fully paid-up, royalty-free, non-sublicensable (except to subcontractors approved in accordance with Section 3.3.6, performing work or otherwise acting on behalf of Atara) license under the Bayer Background Technology and Bayer Background Improvements for the purpose of conducting the Collaboration Activities under and in accordance with this Agreement;

(b) a royalty-free, fully paid-up, irrevocable, perpetual, non-exclusive license - with the right to grant sublicenses (including the right to grant further sublicenses through multiple tiers of sublicensees pursuant to Section 2.4 below) - under any Bayer Results and Joint Results that are Improvements to Atara's proprietary technology relating to the Manufacture of EBV-sensitized T cells for any and all purposes; and

(c) a royalty-free, fully paid-up, irrevocable, perpetual, non-sublicensable license under the Know How within the Bayer Background Technology solely owned by Bayer that is disclosed by any of the Bayer Parties to Atara or Atara's Affiliates, in each case solely for Atara's internal research purposes.

1.149 ***License Grant with respect to New Technology. With respect to New Technology, Atara shall:***

(i) promptly notify Bayer of the acquisition by Atara or any of its Affiliates of any New Technology, including a description of the type of such New Technology, its potential benefits known to Atara with respect to the Exploitation of Licensed Products and [[***]]; and

(ii) within [[***]] after such notification, offer Bayer a license [[***]], such license to form part of the licenses granted under this Agreement, subject to any limitations resulting from the terms of the upstream license as specifically disclosed by Atara to Bayer.

If Bayer agrees to such offer (each such offer a "New Technology Offer") in writing, the licensed rights shall, upon Atara's receipt of Bayer's written acceptance, become subject to the licenses granted to Bayer under Section 2.1, provided that such licensed rights shall be subject to the terms of the applicable upstream license as specifically disclosed by Atara to Bayer. [[***]]. Notwithstanding anything to the contrary contained in this Agreement, this Section 2.3 will terminate in the event that Atara enters into a [[***]], provided that such Third Party is an entity that, immediately prior to the entering into such Change of Control transaction(s), (a) is active in the field of [[***]] and (b) has either (i) a market capitalization of at least [[***]], or (ii) reported revenue of more than [[***]] in the [[***]] month period preceding such Change of Control transaction(s).

1.150 ***Sublicensing. To the extent that the licenses granted under Sections 2.1 and 2.2 are sublicensable, the sublicensing Party shall comply with the following obligations:***

(a) Sublicensing Party's Responsibility. For the avoidance of doubt, any sublicense granted hereunder shall (i) be subject to the terms of this Agreement (including, where applicable, the consent of the applicable upstream licensor) and (ii) not relieve the sublicensing Party from any of its obligations under this Agreement. In addition, any act or omission by a Sublicensee of a Party in connection with this Agreement that, if committed by such Party would be a breach of this Agreement, shall constitute a breach of this Agreement by such Party, provided that Atara shall not have the right to terminate this Agreement pursuant to Section 18.2.2 for an uncured material breach by Sublicensee if (i) such breach was not made at the direction or with the approval of Bayer or a Bayer Affiliate and (ii) upon Atara's request, Bayer causes such Sublicensee to cure such breach within [[***]] days following such notice or, if the Sublicensee fails to cure the breach within such period, terminates the sublicense after the end of the applicable cure period within [[***]] Business Days from Bayer's receipt of a request from Atara to terminate the sublicense. Notwithstanding the foregoing, [[***]].

(b) Notice to Atara.

(i) **Bayer shall provide written notice thereof to Atara within [[***]] Business Days after entering into any sublicense permitted under Section 2.1.1 (other than to an Affiliate of Bayer, provided that should any such Affiliate of Bayer cease to be an Affiliate of Bayer at any time during the Term, Bayer shall within [[***]] Business Days provide written notice to Atara of the applicable sublicense to such former Bayer Affiliate). Bayer will provide to Atara a complete copy of the relevant sublicense agreement within [[***]] days following its execution; provided, however, that the terms of any such sublicense agreement may be redacted to the extent they are not necessary to assess whether Bayer is in compliance with this Agreement. In addition, and notwithstanding the above, if the sublicense agreement includes any sublicense grant from Bayer to a Third Party under the NIH Upstream License, once such sublicense agreement is substantially complete, Bayer shall promptly deliver a copy of such draft to Atara (and Atara shall promptly deliver such copy to NIH) in order to permit NIH to exercise the rights set forth in Section 4 of the NIH Upstream License, it being understood that NIH shall have at least [[***]] Business Days from delivery of such copy by Atara to review and provide comments on such draft, and Atara will promptly provide such comments, if any, to Bayer. Without limiting the foregoing, any such sublicense agreement will be subject to NIH's consent pursuant to the NIH Upstream License, provided that, should Atara fail to provide a response to Bayer within [[***]] Business Days from delivery to Atara of the substantially complete draft referenced above, Bayer may execute and enter into such sublicense agreement.**

*(ii)***Without limiting the foregoing,**

1) any sublicense grant from Bayer to a Third Party that at the time of such grant is engaged in the Development and/or Commercialization, whether on its own or together with its affiliates or Third Parties, of any [[***]] requires Atara's prior written approval, which approval Atara may not unreasonably withhold, condition or delay; and

2) any sublicense grant from Bayer to a Third Party under the NIH Upstream License requires Atara's prior written approval, which approval Atara may only withhold on the grounds of [[***]]; and

3) any sublicense grant from Bayer to a Third Party under the BioVec Upstream License must be in connection with a license under further Licensed Technology and requires Atara's prior written approval, which approval Atara may only withhold on the grounds of [[***]].

provided that, with respect to (ii) and (iii) above, Atara shall use reasonable efforts to request NIH and/or BioVec to provide such approval.

1.151 ***Options to negotiate.***

(a) Option for Sublicense under MOFFITT Upstream License. For [[***]] (the "MOFFITT Option Period"), provided that Atara has no obligation to amend or attempt to amend the MOFFITT Upstream License to extend the term thereof, Atara hereby grants to Bayer an option - which option Bayer may only exercise upon the occurrence of [[***]] - to negotiate with Atara a non-exclusive sublicense under the MOFFITT Upstream License [[***]]. Bayer may exercise such option right by written option exercise notice during the MOFFITT Option Period or the term of this Agreement, whichever ends sooner. Upon Atara's receipt of any such option exercise notice, Atara shall within due course, but in no event later than [[***]] after receipt of the notice, offer Bayer to include the relevant MOFFITT Upstream License in the definition of "Licensed Technology" under this Agreement [[***]], which offer will include, with respect to such MOFFITT sublicense, any deviations from this Agreement that are [[***]] required to ensure consistency with the terms and conditions of the relevant MOFFITT Upstream Licenses, and conditional upon MOFFITT's approval, in each case if and to the extent required for Atara to comply with its contractual obligations under the MOFFITT Upstream License. Atara will use [[***]] efforts to obtain MOFFITT's approval of the sublicense grant to Bayer and, upon Bayer's reasonable request, to negotiate with MOFFITT any further amendments which may be required to grant Bayer the right to use the relevant MOFFITT Upstream License with the same scope as the rights granted by Atara to Bayer under the Licensed Technology pursuant to Section 2.1.

(b) Option for Other CAR-Ts. Bayer will receive the following preferential treatment in the event that Atara or any of its Affiliates has determined to out-license or otherwise grant any Development or Commercialization rights to Third Parties (for clarity, except for ancillary rights granted to contractors, consultants, or other Third Parties engaged by Atara or any of its Affiliates to perform services for or on behalf of Atara or any of its Affiliates) under any Patent Rights or Know How covering any Other CAR-T, in each case to the extent legally possible without breaching any Laws (including on data privacy) or obligations (including contractual obligations) towards Atara's licensors with respect to such Other CAR-T or any other Third Parties who possess any rights, interest or title in any such Other CAR-T, provided that Atara shall not agree on contractual restrictions that limit Atara's ability to grant a license specifically to Bayer whilst not limiting Atara's ability to grant a license to Third Parties generally (for clarity, notwithstanding Atara's right to grant to its contractors, consultants or other Third Parties performing services for Atara or any of its Affiliates or otherwise acting on Atara's or its Affiliates' behalf all rights required for performance of such services):

(i) **Subject to Section 2.5.2.9, during the [[***]] period beginning on the Effective Date, Atara will promptly inform Bayer in writing about the Other CAR-T and the availability of a license thereunder prior to [[***]] and will, upon written request of Bayer to be submitted within [[***]] Business Days upon receipt of Atara's notification, negotiate in good faith a respective agreement with Bayer. Notwithstanding the foregoing or anything to the contrary contained in Section 2.5.2, Atara shall, at all times, be free to enter into negotiations with any Third Parties for a license to any such Other CAR-T following notification of Bayer**

pursuant to this Section 2.5.2.1 and, for clarity, Atara may continue to negotiate with any such Third Parties while separately and concurrently negotiating with Bayer for a license to any such Other CAR-T (including the same Other CAR-T), in each case subject to Bayer's other rights under Section 2.5.2.

(ii) **Subject to Section 2.5.2.9, during the [[***]] period beginning on the Effective Date, Atara hereby additionally grants Bayer a right of [[***]] prior to any grant of rights under such Other CAR-T programs to Third Parties, as described in detail in Sections 2.5.2.3 - 2.5.2.8 below.**

(iii) **If Atara reaches final agreement on a term sheet or, in the absence of any final agreement on a term sheet before a definitive agreement is drafted, on the key business terms with a Third Party with respect to the transfer of, or grant of license or rights under, any Other CAR-T (whether by assignment, license or otherwise) (a "Preliminary Third Party Offer"), Atara shall notify Bayer in writing within [[***]] days of reaching such agreement, which notice shall include [[***]] - for such Preliminary Third Party Offer (a "Preliminary Third Party Offer Notice"). Such notice shall be subject to any applicable confidentiality obligations to such Third Party; provided that Atara shall [[***]]. Bayer shall have [[***]] Business Days after Atara has delivered to Bayer such Preliminary Third Party Offer Notice to deliver a written response to Atara , which response shall include [[***]].**

*(iv)***If Atara determines in good faith that such Preliminary Bayer Offer is [[***]], taking into consideration all material terms thereof but not any terms undisclosed to Bayer, Atara shall so notify Bayer in writing, and (i) Atara will promptly enable Bayer to perform a customary due diligence on the applicable Other CAR- and (ii) within [[***]] days from Bayer's receipt of such notice from Atara – such period to be extended in good faith upon written request of Bayer if both Parties are still in active negotiations – the Parties shall use good faith efforts to [[***]].**

(v) **Prior to entering into a definitive agreement with any Third Party with respect to the transfer of, or grant of license or rights under, the Other CAR-T (whether by assignment, license or otherwise, Atara shall review whether the envisaged final agreement deviates in any respect from [[***]]. In case of any such deviations, Atara shall provide Bayer with a written summary of such differences, including its assessment whether these deviations are material in any of the following manners:**

*(vi)***at least [[***]] percent [[***]] deviation of [[***]] to be paid to Atara or any Affiliate of Atara up to (including) first commercial sale of a licensed product;**

*(vii)***at least [[***]] percent [[***]] change of [[***]] to be paid to Atara or any Affiliate of Atara;**

*(viii)***any material change of [[***]], licensed field or licensed territory; or**

*(ix)***any material change of [[***]], supply and commercialization activities;**

(the "Final Third Party Offer Notice"). [[***]].

(x) **Bayer shall have [[***]] Business Days following Atara's delivery to Bayer of a Final Third Party Offer Notice [[***]] to deliver a written counter-offer to Atara (a "Final Bayer Offer"), and Atara shall within [***]] Business Days upon receipt of such Final Bayer Offer determine in good faith - and provide written notice thereof to Bayer - whether the terms of such Final Bayer Offer are [[***]], taking into consideration all material terms thereof, but not any terms undisclosed to Bayer. If Atara, in its reasonable discretion based solely on a comparison of the Final Third Party Offer Notice and the Final Bayer Offer, determines that the Final Bayer Offer is [[***]], Atara shall so notify Bayer in writing, and (i) Atara will promptly enable Bayer to perform a customary due diligence on the applicable Other CAR-T and (ii) within [[***]] days from Bayer's receipt of such notice from Atara – such period to be extended in good faith upon written request of Bayer if both Parties are still in active negotiations – the Parties shall use good faith efforts to enter into a license agreement with respect to such Other CAR-T on the terms of the Final Bayer Offer. If Atara, in its reasonable discretion based on the principles specified above, determines that the Final Bayer Offer is [[***]], Atara shall so notify Bayer in writing.**

(xi) **If Atara disagrees with Bayer's Objection Notice or if Bayer objects within [[***]] days after receipt of notice of Atara's determination that a Preliminary Bayer Offer or Final Bayer Offer is [[***]], the objecting Party shall notify the other Party of the dispute and the issue shall be referred to each Party's Executive Sponsor who shall meet within [[***]] Business Days (in person, by means of telephone conference, videoconference or other means of communications) and attempt in good faith to resolve such issue within such [[***]] Business Days period (subject only to, in the case of Atara, approval of its board of directors or, in the case of Bayer, approval of the applicable management board, if required). Notwithstanding the foregoing, if [[***]].**

(xii) **If, [[***]] Atara shall thereafter be free to enter into an agreement with such Third Party related to such Other CAR-T based on the Final Third Party Offer. For clarity, Bayer's option with respect to any particular Other CAR-T shall [[***]].**

(xiii) **Notwithstanding anything to the contrary contained in this Agreement, the options and preferential treatment granted to Bayer and Atara's obligations under Section 2.5.2 will, at Atara's option, terminate in the event that Atara enters into a transaction or series of transactions with a Third Party acquiror that constitutes a Change of Control of Atara, provided that such Third Party is an entity that, immediately prior to the entering into such Change of Control transaction(s), (a) is active in the field of [[***]] and (b) has either (i) a market capitalization of at least [[***]], or (ii) reported revenue of more than [[***]] in the [[***]] month period preceding such Change of Control transaction(s). Atara may exercise such option**

by written notice to Bayer within [[***]] following any such Change of Control of Atara. For clarity, the foregoing sentence does not apply in the reverse scenario where Atara acquires a Third Party subject to the Change of Control definition in this Agreement. If Atara's obligations under Sections 2.5.2.2-2.5.2.8 terminate pursuant to this Section 2.5.2.9 during the [[***]]period beginning on the Effective Date and Bayer has not acquired any rights under any Other CAR-T prior to such termination, then Atara shall pay to Bayer an amount of [[***]] within [[***]] days of receipt of the relevant invoice from Bayer, which Bayer may submit on or following the date of termination of such Atara obligations. For clarity, any exercised options under Section 2.5.2 (including all subsections thereunder) shall remain unaffected by any termination of the option rights pursuant to this Section 2.5.2.9. For clarity, and without limiting the foregoing, Section 2.5.2 (including all subsections thereunder) does not and will not apply to any grant of rights to any Third Party resulting from a transaction or series of transactions between Atara and any Third Party acquiror that constitutes a Change of Control of Atara, and Bayer will not receive the preferential treatment and option rights contemplated under Section 2.5.2 in any such scenario.

(c) Additional License. To the extent Bayer wishes to obtain (a) a commercial license under any Know How or Patent Rights Controlled by Atara that is [[***]], or (b) [[***]] under Section 2.1.2, Bayer may, during the term of this Agreement, notify Atara of its desire to enter into negotiations regarding such potential license or expansion by providing written notice to Atara specifying (i) [[***]] or (ii) [[***]] license under the Know How granted to Bayer and its Affiliates under Section 2.1.2, as applicable. Upon Atara's receipt of any such notice and if Atara so agrees in its sole discretion, the Parties shall discuss the terms of a possible license agreement with respect to the relevant intellectual property rights for which Bayer has requested a license.

1.152 ***Technology Transfer.***

(a) Subject to Article 7, which covers the CMC/manufacturing process transfer, within [[***]] days of the Effective Date, Atara shall, and shall cause its Affiliates to, [[***]] deliver to Bayer and / or its designated Affiliate or Sublicensee, in a mutually agreeable form, copies of all written, graphic or electronic embodiments of the Licensed Technology and related Complete Invention Disclosures as well as all cell therapeutics and other materials pertaining to [[***]] for Exploiting Licensed Cell Therapeutics and Licensed Products (hereinafter the "Materials"), [[***]].

(b) Thereafter, on a continuing basis during the term of this Agreement, Atara shall, [[***]] and shall cause its Affiliates to, as soon as reasonably practicable disclose and deliver to Bayer and / or its designated Affiliate or Sublicensee, as soon as reasonably practicable, in a mutually agreeable form, copies of all written, graphic or electronic embodiments of all additional Licensed Technology and / or Complete Invention Disclosures and of all Material which comes into existence from time to time, [[***]].

(c) Without prejudice to the generality of Sections 2.6.1 and 2.6.2, until [[***]] Atara shall, [[***]] at the Atara FTE Rate for each additional FTE hour**,** provide Bayer or its

designated Affiliate or Sublicensee with reasonable technical assistance relating to the use of the Licensed Technology for the purposes of transferring the Licensed Technology from Atara to the applicable Bayer Party, for the purposes of the applicable Bayer Party's acquisition of expertise on the practical application of the Licensed Technology or for the provision of assistance to the applicable Bayer Party on issues arising from time to time during any Exploitation of the Licensed Technology, e.g. with respect to [[***]]. If visits of Atara's representatives to the facilities of the applicable Bayer Party are requested, Atara shall send appropriate representatives to such facilities, provided that Bayer shall reimburse Atara for its reasonable and verifiable out-of-pocket expenses of travel and accommodation for such representatives that have been pre-approved by Bayer in writing.

1.153 ***Good Faith Efforts to Control Required Intellectual Property. Upon Bayer's written request, Atara shall use good faith efforts to acquire licenses under Know How and Patent Rights that become controlled by MSK and NIH after the Effective Date, to the extent that those intellectual property rights are (i) not yet included in Atara's licenses under the MSK Upstream Licenses and the NIH Upstream License, as applicable, and (ii) reasonably required for the Exploitation of Licensed Products. This obligation is subject to good faith agreement between Atara and Bayer on sharing of any additional license fees to be paid for the additional licenses.***

1.154 ***No Other Licenses. Except as expressly provided in this Agreement, neither Party shall be deemed, whether by estoppel, implication or otherwise, to have granted the other Party any license or other right with respect to any intellectual property rights of such Party, its Sublicensees, its upstream licensors, or its or their Affiliates. And each Party hereby covenants, on behalf of itself and its Affiliates, not to Exploit any intellectual property rights licensed to such Party or its Affiliates under this Agreement (and, to the extent such Party sublicenses any such intellectual property rights to any Sublicensees hereunder, shall cause such Sublicensees, not to Exploit any such intellectual property rights) except as expressly permitted herein.***

GOVERNANCE

1.155 ***Purpose and Scope of Collaboration. The Parties are entering into a collaboration, with the intent of***

(a) further developing ATA3271 [[***]] (hereinafter the "Research Activities") in accordance with the Research Plan; and

(b) developing the CMC process for clinical supply manufacture with respect to ATA3271 (hereinafter the "CMC Activities") in accordance with the CMC Plan.

1.156 ***Collaboration Plans. Each of (a) the Research Activities and (b) the CMC Activities shall be carried out during the relevant Collaboration Term in accordance with the relevant Collaboration Plan. Each Collaboration Plan sets forth the responsibilities and activities to be performed by the Parties, details regarding each of the Parties' deliverables and timetables for delivery of such deliverables. The Collaboration Plans may be modified by the JSC in***

accordance with Section 3.5, provided that no such modification may materially increase the other Party's obligations under such Collaboration Plan unless the Parties have agreed to such increase in accordance with Section 21.11. To the extent any terms in any Collaboration Plan should at any time conflict with the terms of this Agreement, the terms of this Agreement shall prevail.

1.157 ***Performance of the Collaboration Activities.***

(a) Each Party shall [[***]] perform those parts of the Collaboration Activities that it is responsible for in the manner and within the times frame set forth in the relevant Collaboration Plan and otherwise in accordance with the terms of this Agreement.

(b) Each Party shall maintain and make available for the Collaboration Activities all laboratories, offices and other facilities that are necessary to carry out its responsibilities under the relevant Collaboration Activities pursuant to the relevant Collaboration Plan.

(c) Reports.

(i) **Each Party shall submit to the other Party reports on its activities under each of the (a) Research Activities and (b) CMC Activities, and shall provide to the other Party deliverables of such activities, each with information, frequency, within the timelines and with a format as specified in the relevant Collaboration Plan.**

(ii) **In addition, each Party's Alliance Manager shall, with respect to each of the (a) Research Activities and (b) CMC Activities,**

1) provide the members of the JSC with written updates regarding its Party's activities under the relevant Collaboration Plan, including summary results and analyses thereof, prior to each JSC meeting; and

2) on a [[***]] basis until the end of the relevant Collaboration Term, provide the JSC with a written report regarding its Party's activities under the relevant Collaboration Plan, including protocols, experimental procedures, results, analyses thereof and conclusions for the previous [[***]] month period (or in the case of the report at the end of the relevant Collaboration Term for the period since the previous written report) in a mutually agreed format.

At the request of an Alliance Manager, the Alliance Managers and members of the responsible teams of both Parties will discuss any questions regarding the contents of such reports.

(d) Records. Each Party shall prepare and maintain complete and accurate written records, in sufficient detail and in good scientific manner appropriate also for patent and regulatory purposes, pertaining to its respective activities under the Collaboration Activities. Such records shall properly reflect all work done, results achieved and inventions discovered and reduced to practice in the performance of its works under the Collaboration Activities and shall be retained by such Party for at least [[***]] years after the expiration or

termination of this Agreement, or for such longer period as may be required by any Laws. Each Party shall make such records available for inspection by the other Party at all reasonable times and deliver copies of such records to the other Party at such other Party's reasonable request.

(e) Place of Performance. Atara shall perform those parts of the Collaboration Activities that it is responsible for exclusively at [[***]]; as applicable.

(f) Subcontracting. Atara shall not subcontract any parts of the Collaboration Activities to any Third Party without the prior written consent of Bayer. Bayer, however, hereby consents to Atara's Affiliates and, solely with respect to activities that MSK is responsible for pursuant to the ATA2271 Plan, to MSK acting as subcontractors of Atara. In case of any written consent of Bayer, if required, to the use of a specific subcontractor for a specific activity, unless explicitly otherwise agreed, the consent will be deemed given under the condition that such contractor of the other Party enters or has entered into an agreement obligating such contractor to all confidentiality, publication and intellectual property-related provisions of this Agreement, applicable to Atara. Each Party shall be solely responsible for the supervision and direction of contractors performing activities designated as such Party's task under the Collaboration Plan and shall be solely liable for the performance of such activities by such contractors in compliance with this Agreement. Atara will impose on any subcontractor who supplies drug product or any parts thereof sustainability obligations that are substantially equivalent to the sustainability requirements specified in the Bayer Supplier Code of Conduct, which is attached hereto as Exhibit 3.3.6 (the "Bayer Supplier Code of Conduct").

(g) Each Party agrees to perform all its activities within the Collaboration Activities in good scientific manner and to comply with all Laws applicable to the performance of the activities that it is responsible for under the Collaboration Plans.

(h) Neither Party shall use in any capacity the services of anyone debarred, disqualified, blacklisted or banned or under investigations or threat of investigations by any regulatory authority for debarment, disqualification, blacklisting or any similar regulatory action in any jurisdiction anywhere in the world. Furthermore, each Party represents and warrants that neither such Party nor its employees, agents or representatives involved in the performance of the Collaboration Activities have been debarred, disqualified, blacklisted or banned by any regulatory authority, nor are they currently, to such Party's Knowledge, the subject of such a debarment, disqualification, blacklisting or banning proceeding. During the term of the Agreement, each Party shall promptly notify the other Party should it or any of its employees, agents or representatives involved in the performance of the Collaboration Activities become the subject of such debarment, disqualification, blacklisting or banning proceeding.

(i) Atara is expected to [[***]] organize its activities under the Collaboration Plans in a manner that [[***]] in line with the Bayer Supplier Code of Conduct, provided that in the event of any conflict between the Bayer Supplier Code of Conduct and a Collaboration Plan, the Collaboration Plan shall govern. Bayer shall have the right to audit the sustainability performance of Atara, either by written assessment (online, paper

questionnaire, etc.) or, upon reasonable advance written notice, by an onsite audit conducted at a mutually agreeable time and in a mutually agreeable manner, executed directly by Bayer or by a Third Party auditor reasonably acceptable to Atara, provided that any such Third Party auditor has entered into an agreement obligating such Third Party auditor to all confidentiality, publication and intellectual property-related provisions of this Agreement, applicable to Bayer. The sustainability performance will be evaluated by comparing it with the Bayer Supplier Code of Conduct principles.

(j) Material Transfer.

*(i)***From time to time, Bayer may transfer materials to Atara for purposes of the Collaboration Activities.**

*(ii)***Atara understands that materials transferred by Bayer are experimental in nature and Bayer does not make any representation or warranty, express or implied, as to the identity, ownership, purity, utility, safety or activity of such biological materials.**

*(iii)***Atara shall use Bayer's materials only for the purposes of performing its obligations or exercising its rights under this Agreement. Atara shall not reverse engineer or analyze (except to the extent expressly permitted in the Collaboration Plan and then only for the purposes of the Collaboration Activities) the material or otherwise attempt to determine the identity, structure, or composition of the material, nor will Atara permit or assist others to do so.**

*(iv)***Atara shall not transfer Bayer's material to any Third Party, except to contractors or collaborators of Atara for the purposes authorized by this Agreement upon prior written notice of such transfer to Bayer.**

1.158 ***Responsibility for Expenses for Conduct of the Collaboration Activities. Except as may be specifically agreed to in writing by the Parties, Bayer shall bear its own costs and expenses incurred in the performance of the activities to be performed by it under the Collaboration Plans and the reimbursement upfront fee to be paid by Bayer to Atara pursuant to Section 9.2 shall, except as otherwise specified in this Agreement, be the complete reimbursement for Atara's costs and expenses incurred in the performance of Collaboration Activities identified as [[***]] under the Collaboration Plans. For clarity, neither Party shall be under any obligation to incur any cost other than as necessary to fulfill such Party's obligations under this Agreement.***

1.159 ***Revisions or Expansions to Collaboration Plan.***

(a) Any revision or expansion to the Collaboration Plan that may be requested by either of the Parties during the relevant Collaboration Term shall be discussed by the JSC. This includes, without limitation, discussions regarding the effect any such requested revision or expansion will have on the deliverables (including timing) to be provided under the relevant Collaboration Plan and the allocation of Atara's and / or Bayer's resources for performance of its activities under the relevant Collaboration Activities.

(b) The JSC shall have the authority to amend the relevant Collaboration Plan per such Party's request, and such amendment shall be incorporated into the relevant Collaboration Plan by reference. For clarity, this does not include any right of the JSC to change any terms of this Agreement other than solely within the relevant Collaboration Plan.

If the JSC determines that a Party's request refers to matters that do not materially change the Collaboration Plan and such changes do not materially impact the amount of resources allocated to such activity, the JSC shall have the authority to amend the Collaboration Plan per such Party's request, and such amendment shall be incorporated into the Collaboration Plan by reference.

If the JSC determines that the request refers to matters that materially change the Collaboration Plan, or that such changes materially impact the amount of resources allocated to such activity, the JSC shall prepare and present to the Parties' respective Executive Sponsors a detailed written proposal for such revision or expansion to the Collaboration Plan. If such proposal is approved by the Executive Sponsor of each of the Parties, the amended Collaboration Plan shall be agreed upon pursuant to Section 21.11.

1.160 ***Governance.***

(a) Alliance Sponsors. Each party shall designate an executive as sponsor for the alliance (each such executive, an "Alliance Sponsor"). The Alliance Sponsors shall meet and confer as often as they deem appropriate to maintain the health, priority, and direction of the relationship and to proactively solve issues as necessary. The initial Alliance Sponsor designated by Atara is the Vice President, Corporate Strategy and Business Development of Atara, and the initial Alliance Sponsor designated by Bayer is the Vice President, Head of Oncology Strategy & Early Commercialization of Bayer.

(b) Alliance Managers. As soon as practicable after the Effective Date, each Party shall nominate a representative to act as its alliance manager under this Agreement (the "Alliance Manager"). The Alliance Managers shall serve as the key contact point between the Parties. Each Alliance Manager shall be a permanent non-voting member of the Joint Steering Committee and any subcommittee(s). A Party may replace its Alliance Manager at any time by providing written notice to the other Party.

(c) Joint Steering Committee. Within [[***]] days after the Effective Date the Parties shall establish a joint steering committee (the "Joint Steering Committee" or "JSC").

(i) **Composition. The JSC shall be composed of an equal number of representatives [[***]] from each Party plus the Alliance Manager(s) in a [[***]] capacity. Each JSC representative shall have appropriate experience, knowledge and authority within such Party's organization to carry out the duties and obligations of the JSC. Each Party shall name its initial JSC representatives and designate one of its representatives as the co-chair (each, a "Co-Chair") for that Party.**

(ii) **Responsibilities of the JSC. The JSC provides strategic direction and operational oversight to the Alliance, evaluates performance, recommends corrective action and shall act as the point of escalation for issues that cannot be resolved at subcommittee or sub-team levels. Within [[***]] days of the execution of the agreement, the JSC shall jointly establish a charter (the "JSC Charter") that details specific responsibilities and such JSC Charter will be updated annually to ensure it is focusing on key activities and contractual obligations. Initial considerations for the JSC Charter include:**

1) monitoring performance of this Agreement as well as progress of the Collaboration Activities compared to the goals defined in the Collaboration Plans and deciding on corrective action, where required;

2) serving as the principal means by which each Party keeps the other Party informed about the status of those parts of the Collaboration Activities within its responsibilities;

3) reviewing and discussing as to whether the deliverables have been achieved;

4) agreeing on changes to the existing Collaboration Plans - including, with respect to the Research Plan in the event of [[***]] - in each case, which do not materially increase or decrease Atara's or Bayer's obligations, provided that, for clarity, the JSC shall not have the authority to [[***]];

5) recommending modifications to the Collaboration Plan which materially increase or decrease Atara's or Bayer's obligations, or any other amendments to this Agreement;

6) agreeing on changes to the ATA2271 Plan, which changes shall be subject to MSK approval prior to taking effect, provided that Atara shall use reasonable efforts to obtain such MSK approval;

7) identifying the Bayer Background Technology, if any, to be used in connection with the Collaboration Activities;

8) acting as the point of escalation for issues that cannot be resolved otherwise; and

9) performing such other functions as are specifically assigned to the JSC in this Agreement.

(iii) **Operation of the JSC.**

1) JSC Meetings. The JSC shall meet (in person, by means of telephone conference, videoconference or other means of communications) as deemed necessary by the Co-Chairs but at least once Quarterly through the IND filing for the first allogeneic Licensed Product, and semi-annually thereafter (unless the Parties mutually agree otherwise). The location for in-person meetings, if any, shall alternate between the facilities of the Parties (or such other location as is mutually agreed by the respective

Co-Chairs of the JSC). A kick-off meeting of appropriate duration should be scheduled within [[***]] after the Effective Date.

2) Preparation of Meetings. In close interaction with the Co-Chairs the Alliance Managers are responsible for the scheduling, planning and preparation of the JSC meetings. Particular responsibilities of the Alliance Managers include:

a) JSC-aligned scheduling of the regular and additional meetings of the JSC;

b) preparation of a JSC-aligned meeting agenda; and

c) providing the JSC members with advance notices for all scheduled meetings, meeting agendas and other relevant materials reasonably in advance of such meeting.

(iv) **Meeting Attendees / Guests. In addition to the members of the JSC, the Co-Chairs of each subcommittee (if any) and a reasonable number of additional representatives of a Party or advisors may attend the meetings of the JSC in a non-voting capacity for the limited purpose of providing input with respect to a particular matter on the agenda. A list of all representatives of each Party expected to attend the meeting shall be included on the meeting agenda and distributed to the JSC prior to the relevant meeting.**

(v) **Meeting Minutes. Responsibility for preparing the definitive minutes of each meeting of the JSC shall alternate between the Alliance Managers of the Parties. The Alliance Managers shall prepare and circulate a draft of the minutes of each meeting to all members of the JSC for comments within [[***]] Business Days after such meeting. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting and shall document all actions and decisions approved by the JSC at such meeting. The Parties shall promptly discuss any comments on such minutes and finalize the minutes promptly. Formal joint approval of the minutes should take place no later than the date of the next meeting of the JSC. Meeting minutes for subcommittees are the responsibility of the Co-Chairs of the respective subcommittee.**

(vi) **Meeting Costs. Costs incurred by each Party in connection with its participation at any meetings of the JSC shall be borne [[***]].**

(vii) **Decision Making by the JSC. Decisions of the JSC required to be made by this Agreement shall be made by vote, with each Party's voting representatives on the JSC collectively having one (1) vote. No vote may be taken unless at least one (1) of each Party's representatives participates.**

(viii) **Limited Powers of the JSC. The JSC shall have only the powers assigned expressly to it in this Agreement, and shall not have the power to (i) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (ii) modify or amend the terms and conditions of this Agreement subject to the JSC's right to agreeing on non-material modifications to the Collaboration Plans. In furtherance thereof, each Party shall retain the rights,**

powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JSC.

(d) Subcommittees. The JSC shall have the right to establish and disband subcommittees as deemed necessary by the JSC depending on the scope, nature and phase of the alliance described in this Agreement. When establishing such subcommittees, the JSC shall specify the composition, responsibilities and duration of such subcommittee. Unless specified at the time a subcommittee is established by the JSC, the provisions of Section 3.6.3 shall apply *mutatis mutandis* to each such subcommittee formed pursuant to this Section 3.6.4.

1.161 ***Escalation.***

(a) If any subcommittee established by the JSC is unable to decide or resolve unanimously any matter properly presented to it for action within [[***]] days of such matter being referred to it for action, at the written request of either Party, the issue shall be referred to the JSC who shall meet within [[***]] Business Days (in person, by means of telephone conference, videoconference or other means of communications) and attempt in good faith to resolve such issue (subject only to, in the case of Atara, approval of its Executive Sponsor or, in the case of Bayer, approval of the applicable management board, if required).

(b) If the JSC is unable to decide or resolve unanimously any matter properly presented to it for action within [[***]] Business Days of such matter being referred to it for action, at the written request of either Party, the issue shall be referred to the Executive Sponsors who shall meet within [[***]] Business Days (in person, by means of telephone conference, videoconference or other means of communications) and attempt in good faith to resolve such issue (subject only to, in the case of Atara, approval of its board of directors or, in the case of Bayer, approval of the applicable management board, if required). Notwithstanding the foregoing, if the Executive Sponsors cannot resolve such matter within [[***]] Business Days of the date such matter is first referred to them, then, [[***]]:

[[***]];

(ii) [[***]];

(iii) notwithstanding any other provision of this Agreement to the contrary, [[***]]; and

(iv) notwithstanding any other provision of this Agreement to the contrary, [[***]].

In each case, [[***]].

1.162 ***Termination of the JSC. The JSC shall continue to exist until the latter of: (i) the [[***]]; or (ii) [[***]]***

DEVELOPMENT

1.163 ***Responsibility. With the exception of the ATA2271 Phase 1 Clinical Trial and any other Phase 1 Clinical Trial relating to ATA2271 mutually agreed between the Parties after the Effective Date, and subject to the terms and conditions of this Agreement, Bayer shall be solely responsible for the Development of the Licensed Cell Therapeutics and / or Licensed Products in the Field in the Territory, at Bayer's sole discretion (subject to Section 4.4) and Bayer's sole expense, including for the avoidance of doubt:***

(a) determining, planning and implementing the Development plans and strategies for the Licensed Cell Therapeutic and / or Licensed Product; and

(b) conducting, and determining the timing and scope of and schedule for, all Clinical Trials related to the Licensed Cell Therapeutic and / or Licensed Product (including performing cell selection for allogeneic Licensed Products, which, for clarity, Atara is not responsible to perform),

in all cases, whether performed by or on behalf of Bayer or any other Bayer Party or Third Party appointed by Bayer.

1.164 ***Atara's ATA2271 Development Responsibilities.***

(a) Atara (in collaboration with MSK) will [[***]] continue, and will [[***]] cause MSK to continue, [[***]] the ATA2271 Phase 1 Clinical Trial in the manner outlined within the ATA2271 Plan and any other Phase 1 Clinical Trial relating to ATA2271 in the manner pre-agreed upon (including with respect to any financial terms) with Bayer. Atara will report on its activities under such Phase 1 Clinical Trial and results thereof both through written reports and through oral communication (including via the JSC), and shall provide Bayer deliverables of such activities and results, each with information, frequency, within the timelines and with a format as specified in the relevant ATA2271 Plan. This includes that Atara will submit to Bayer all Regulatory Documentation and all other study data relating to the ATA2271 Phase 1 Clinical Trial within due course, but in no event later than within [[***]] Business Days after such documents and data are received or generated by Atara. Upon request of Bayer, Atara will enable Bayer scientists to participate as observing members in any material development-related activities of Atara and to the extent that Atara has the right to do so, any material development-related activities of MSK, said participation being subject to MSK's approval. Atara will [[***]] obtain such approval from MSK and will, upon Bayer's written request, inform Bayer about the steps taken to obtain such MSK approval and the status of the approval process.

(b) After completion of [[***]], Bayer shall be solely responsible, at its sole discretion, for continuing the ATA2271 clinical development and Atara will take all steps reasonably required to enable Bayer to take over such program in a mutually agreeable manner.

(c) For clarity, all materials, documents and data generated within the ATA2271 clinical development, as described above, form part of the Licensed Technology and, consequently, Bayer has the exclusive right to use such materials, documents and data for Exploitation of Licensed Cell Therapeutics and Licensed Products in the Field in the Territory.

1.165 ***Cooperation of Atara. Bayer acknowledges Atara's expertise and experience in preclinical development, CMC/manufacturing, regulatory matters and early clinical development for cell therapy products. Therefore, Atara shall reasonably cooperate with and provide assistance to Bayer in connection with Bayer's Development activities with respect to the Licensed Cell Therapeutic and / or Licensed Product, in accordance with Section 2.6.3.***

1.166 ***Efforts.***

(a) Bayer shall use Commercially Reasonable Efforts to Develop [[***]] in each of the Major Market countries. For clarity, Bayer shall not have any Development obligations for any additional indication or in any other country.

(b) Without limiting the foregoing, with respect to Licensed Products covered by Licensed Patents in-licensed by Atara under the NIH Upstream License, the following applies:

1) "Commercially Reasonably Efforts", for the purposes of this provision, shall include [[***]].

2) Bayer will provide Atara written [[***]] reports on its product development progress [[***]]within [[***]] days after the end of each Calendar Year. These progress reports shall include, but not be limited to: [[***]]. Bayer agrees to provide any additional information reasonably required by the NIH to evaluate Bayer's compliance with its diligence obligation under the NIH Upstream License.

3) Bayer shall report to Atara the dates for achieving the [[***]] and the First Commercial Sale in each country in the Territory within [[***]] days of such occurrences.

REGULATORY

1.167 ***General responsibility. Except as specifically set forth in Section 5.2, subject to the terms and conditions of this Agreement, Bayer shall be solely responsible for, at Bayer's sole expense (except as set forth elsewhere in this Agreement, including its Exhibits):***

(a) determining, planning and implementing the regulatory plans and strategies for the Licensed Product(s);

(b) preparing and maintaining the "Company Core Data Sheet" for the Licensed Product(s);

(c) either directly or through its Affiliates or Sublicensees, making all regulatory filings with respect to the Licensed Product(s);

(d) preparing, filing, and holding all INDs and Regulatory Approvals throughout the Territory in the name of either itself or its Affiliates or Sublicensees, with the exception of the IND data package up to IND Readiness for ATA3271, which Atara shall provide to Bayer; and

(e) all interactions with Regulatory Authorities with respect to the Licensed Product(s), including all submissions, meetings and discussions in all cases, whether performed by or on behalf of Bayer or any other Bayer Party or Third Party appointed by Bayer.

1.168 ***Responsibility for ATA2271 Phase 1 Clinical Trial. Atara (in collaboration with MSK) shall be [[***]] responsible for all regulatory filings with respect to the ATA2271 Phase 1 Clinical Trial as well as the IND relating to ATA2271, up to [[***]]. Sections 4.2.1 – 4.2.3 apply mutatis mutandis.***

1.169 ***Cooperation of Atara. Atara shall [[***]] cooperate with and provide assistance (excluding any research or development work, which is addressed in Section 2.6.3, or any drafting with respect to the content of any IND or BLA) to Bayer solely to address regulatory questions during the review of IND or BLA filings or any other filing with a Regulatory Authority, in each case with respect to a Licensed Product, including by promptly executing any required documents, providing access to personnel and providing all such documentation as Bayer may reasonably require and request from time to time, as well as by [[***]] to ensure that Bayer Parties obtain from MSK all authorizations that may be required to fully benefit from the results of any ATA2271 clinical development (including any cross references to the ATA2271 IND in an IND filing for another Licensed Cell Therapeutic) Atara shall cooperate with the Bayer Parties, as may be requested by Bayer, in connection with any inspection by a Regulatory Authority relating to a Licensed Product including any inspection prior to approval of an BLA for any Licensed Product.***

1.170 ***Assignment of Regulatory Documentation. Notwithstanding Atara's earlier reporting obligations pursuant to Section 4.2 of this Agreement, upon [[***]] Atara shall assign, and shall [[***]] cause MSK to assign, to Bayer all of its and MSK's rights, title and interest in and to all Regulatory Documentation, including, to the extent permitted by Law, all Regulatory Approvals and INDs Controlled by Atara or MSK as of the Effective Date and from time to time during the term of this Agreement. Atara shall, and shall [[***]] cause MSK to, duly execute and deliver, in each case within [[***]] Business Days of the Effective Date, such instruments, and shall do, and shall [[***]] cause MSK to do, such acts and things, including the filing of such assignments, agreements, documents and instruments as Bayer may reasonably request from time to time in connection with Bayer's rights under this Section 5.4. Atara shall also provide to Bayer all updates to such Regulatory Documentation within [[***]] Business Days of their first becoming available to Atara.***

1.171 ***Rights of Reference.***

(a) Right of Reference for Atara. Atara and its Affiliates and their designees will have, and Bayer (on behalf of itself and its Affiliates) hereby grants, and shall cause all other Bayer Parties to grant, to Atara and its Affiliate and their designees, access and a "Right of Reference or Use" as that term is defined in 21 C.F.R. § 314.3(b) (without any further

action required on the part of Atara, its Affiliates or contractors, whose authorization to file this consent with any Regulatory Authority is hereby granted) in connection with the development of products of Atara and its Affiliates to all Regulatory Documentation relating to any Licensed Cell Therapeutic or Licensed Product, or any components thereof, controlled by or on behalf of any Bayer Parties and all data contained or referenced therein, and agrees to sign and cause the other Bayer Parties to sign, any instruments reasonably requested by Atara in order to effect such grant.

(b) Right of Reference for Bayer. Atara hereby grants and shall [[***]] cause MSK and Atara's and MSK's Affiliates grant to Bayer Parties a "Right of Reference or use" as that term is defined in 21 C.F.R. § 314.3(b), without any further action required on the part of Bayer Parties or their contractors (whose authorization to file this consent with any Regulatory Authority is hereby granted), in connection with the development of Licensed Cell Therapeutics or Licensed Products to all Regulatory Documentation relating to ATA2271 or any components thereof and all data contained or referenced therein, and agrees to sign, and shall [[***]] cause MSK and Atara's and MSK's Affiliates to sign, any instruments reasonably requested by Bayer Parties in order to effect such grant. If Bayer wishes to obtain a "Right of Reference or use" to any other regulatory filing Controlled by Atara, Bayer shall so notify Atara in writing, and, provided that Atara has the rights necessary to grant Bayer any such rights and that such additional Right of Reference or use is reasonably required to Develop the Licensed Cell Therapeutic or Licensed Product without any unnecessary delay or significant additional cost, Atara shall consider, in good faith, Bayer's request for an additional grant of such rights to Bayer and shall not unreasonably withhold its consent to such request.

COMMERCIALIZATION

1.172 ***Commercialization.***

(a) Responsibility. Subject to the terms and conditions of this Agreement, Bayer shall be solely responsible for the Commercialization of the Licensed Product in the Field in the Territory at Bayer's sole expense (except as set forth elsewhere in this Agreement), including, for the avoidance of doubt, the planning and implementation, distribution, booking of sales, pricing and reimbursement, in all cases, whether performed by or on behalf of Bayer or any other Bayer Party or Third Party appointed by Bayer.

(b) Efforts. Bayer shall use Commercially Reasonable Efforts to Commercialize [[***]] in each Major Market.

(c) Additional Restrictions relating to NIH Upstream License. Solely with respect to Licensed Products that are covered by Licensed Patents under the NIH Upstream License, Bayer shall use Commercially Reasonable Efforts to (i) make Licensed Products reasonably accessible to the United States public, (ii) make reasonable quantities of Licensed Products available to patient assistance programs, (iii) develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the Licensed Products or medical aspects of the prophylactic and therapeutic uses of the Licensed Products, and (iv) upon request of Atara or NIH, supply NIH with inert samples

of the Licensed Products or their packaging for educational and display purposes only, provided that, unless explicitly stated otherwise in the request, such samples or packaging shall be mailed to: [[***]]. Furthermore, solely with respect to Licensed Patents under the NIH Upstream License that cover Licensed Products (if any), Bayer and all Bayer Parties agree to mark the Licensed Products, or their packaging sold in the United States with the applicable U.S. patent numbers and similarly to indicate "“Patent Pending"” status of such Licensed Patents.

(d) Commercialization Plan. At least [[***]] days in advance of the anticipated [[***]] of a Licensed Product in [[***]] in the Territory, Bayer shall prepare and submit to Atara a written plan setting forth the activities to be undertaken with respect to the Commercialization of Licensed Products (the "Commercialization Plan"), which shall describe in reasonable detail Bayer's Commercialization activities for the rest of the relevant [[***]]. Thereafter, Bayer shall prepare and submit to Atara for the rest of the term of the Agreement a Commercialization Plan on any new [[***]] no later than [[***]] days after [[***]].

MANUFACTURING

1.173 ***Except as specifically set forth in Sections 7.2 and 7.3, subject to the terms and conditions of this Agreement, Bayer shall be solely responsible for and bear all costs of the manufacture, storage, distribution and supply of the Licensed Products in the Field in the Territory.***

1.174 ***Notwithstanding the foregoing, Atara will be responsible for the performance of the CMC Activities in accordance with the CMC Plan.***

1.175 ***Within [[***]] days following the Effective Date, the Parties shall enter into a Phase 1 – 2 Manufacturing and Supply Agreement pursuant to which [[***]]. The key terms of the Phase 1 – 2 Manufacturing and Supply Agreement and the Phase 3 Manufacturing and Supply Agreement are set forth in Exhibit 7.3, attached hereto. Such Manufacturing and Supply Agreements shall include as an annex a Quality Agreement containing terms and conditions regarding quality assurance/quality control and compliance with cGCP, cGLP and cGMP, as applicable.***

PHARMACOVIGILANCE

1.176 ***General. Both Parties agree to promptly exchange all information that relates to the safety of the Licensed Product and to comply with all Laws relating to the Licensed Product concerning drug safety.***

1.177 ***Pharmacovigilance Agreement. In furtherance of Section 8.1, the Parties shall negotiate and execute a pharmacovigilance agreement within [[***]] days of the Effective Date. Bayer will create and maintain a master drug safety database which shall cross-reference adverse events relating to the Licensed Product occurring anywhere in the world. Bayer shall be the sole owner of the master drug safety database. Atara shall submit all data collected by it with respect to adverse events relating to the Licensed Product to Bayer in accordance with the timelines set forth in the pharmacovigilance agreement. After transfer of***

the [[***]] to Bayer, Bayer shall be responsible for all reporting of adverse events pursuant to Law with respect to the Licensed Products.

FINANCIAL PROVISIONS

1.178 ***License Upfront Payment. In consideration of the licenses granted by Atara to Bayer under the Agreement, Atara shall be entitled to invoice Bayer for a one-time license upfront payment of US$45,000,000 (in words: forty-five million U.S. dollars) (the "Upfront License Payment") on or after the Effective Date, which Upfront License Payment reflects the aggregate value of the Licensed Technology as set forth in Exhibit 9.1.***

1.179 ***Reimbursement Upfront Payment. As reimbursement for Atara's expenses for activities identified as [[***]] under the Collaboration Plans, Atara shall be entitled to invoice Bayer for a one-time reimbursement upfront fee of US$15,000,000 (in words: fifteen million U.S. dollars) on or after the Effective Date.***

Should the preclinical development of [[***]] be stopped early ([[***]]), then any unused portion of such reimbursement upfront fee will be used for [[***]], provided that the decision on the [[***]] and the related Research Plan shall be made by the JSC pursuant to Section 3.6.3.2(iv).

1.180 ***Remuneration for Further Research Activities. In consideration for the conduct of the activities identified as [[***]] under the Research Plan, Atara shall be entitled to invoice Bayer for an amount equal to US$5,000,000 (in words: five million U.S. dollars) in the following installments:***

[[***]] percent [[***]] upon initiation of any one of the activities identified as [[***]] under the Research Plan;

(ii) [[***]] percent [[***]] upon Atara's delivery of Atara's qualification report following [[***]], such report, as applicable, to be consistent with the table of contents set forth in Exhibit 1.72 and to be in a form consistent with the reporting template identified as "Pre-clinical Technical Report" disclosed by Atara to Bayer prior to the Effective Date; and

(iii) [[***]] percent [[***]] upon Atara's delivery of the last qualification or study report, as applicable, following [[***]], such report, as applicable, to be consistent with the table of contents set forth in Exhibit 1.72 and to be in a form consistent with the reporting template identified as "Preclinical Technical Report" disclosed by Atara to Bayer prior to the Effective Date.

1.181 ***Milestones.***

(a) Development and Regulatory Milestones for Licensed Products other than [[***]] Licensed Products. Upon the first (1st) achievement of any of the following milestone

events for a human therapeutic Licensed Product that is not an [[***]] Licensed Product, Atara shall be entitled to invoice the following one-time payments to Bayer:

[[***]]

For [[***]] met with a [[***]] Licensed Cell Therapeutic or Licensed Product that is [[***]], the respective milestone payments above shall become due, each with an [[***]]. For [[***]] met with a [[***]] Licensed Cell Therapeutic or Licensed Product that is a [[***]], the respective milestone payments above shall become due, each with an [[***]]. For [[***]] met with a [[***]] Licensed Cell Therapeutic or Licensed Product that is a [[***]], the respective milestone payments above shall become due, each with an [[***]].

For clarity, [[***]] will be deemed to have been met with a Systemic Product [[***]] upon [[***]].

Notwithstanding Section 9.4.5.1, in the event a Phase 2 Clinical Trial seeking accelerated Regulatory Approval is initiated, the milestone payments under [[***]] shall be due upon the earliest of [[***]]. Bayer shall provide written notice to Atara of any of the events described in clauses (a) – (c) of the preceding sentence within [[***]] days following the occurrence of the relevant event.

For clarity, any inference or reference to a "first, "second" or "third" Tumor Type above, shall be construed to mean the "first", "second" or "third" Tumor Type that achieves the applicable milestone event, regardless of how many other Tumor Types have been previously pursued with respect to the same or other Licensed Products without achieving the applicable milestone event; this means, [[***]].

In the event that [[***]], Atara is entitled to invoice an amount of [[***]] to Bayer together with [[***]]. Bayer shall make such payment within [[***]] days from [[***]]. For clarity, [[***]]. In the event that, following such payment by Bayer, [[***]], then [[***]].

(b) Development and Regulatory Milestones for [[***]] Licensed Products. Upon the first achievement of any of the following milestone events for the first human therapeutic [[***]] Licensed Product (including a Licensed Product comprising [[***]]), [[***]] Atara shall be entitled to invoice the following one-time payments to Bayer:

[[***]]

(c) Sales Milestones. Upon the first (1st) occurrence of aggregate annual Net Sales set out below with respect to a Licensed Product in the Field in the Territory, Bayer shall make the following payments to Atara:

[[***]]

(d) Reporting on Milestone Achievement and Payment. Bayer shall provide written notice to Atara of (a) any occurrence of any of the development milestones set forth above no later than [[***]] days following the occurrence of the relevant milestone, and (b) any occurrence of any of the sales milestones set forth above with the royalty report to be provided by Bayer for the respective Quarter pursuant to Section 9.5.5, and shall, upon receipt of an invoice pursuant to Section 9.6, make the associated milestone payments in accordance with Section 9.6.

(e) Limitation on Milestones. For the avoidance of doubt:

(i) **The Development and Regulatory Milestones are intended to be successive on a country-by-country or region-by-region basis, as applicable; in the event that Bayer skips any of such milestones on a country-by-country or region-by-region basis, as applicable, Bayer shall be deemed to have achieved such skipped milestone when it achieves the next successive Development and Regulatory Milestone for the relevant Licensed Product.**

*(ii)***No milestone payment will be made more than once per Licensed Product (as opposed to another Licensed Product);**

*(iii)***No additional milestone payments shall be due in respect of subsequent or repeated achievements of any milestone(s), irrespective of the number of countries in which such milestone has been achieved, or in respect of any further indications not explicitly specified within the milestones listed under Section 9.4.1 and 9.4.2 above;**

*(iv)***No additional milestone payments shall be due in respect of any Combination Licensed Product where the milestone has already been paid on a Licensed Product; and**

*(v)***Each milestone payment shall be due whether the corresponding milestone event has been achieved by Bayer, its Affiliates or Sublicensees.**

1.182 ***Royalties.***

(a) Royalty Rates. Subject to the terms and conditions set forth in this Section 9.5 and elsewhere in this Agreement, Bayer shall pay to Atara royalties on aggregated annual Net Sales of each such Licensed Product sold in the Territory during the Royalty Term in the following amount:

[[***]]

For the avoidance of doubt, the cumulative Net Sales value shall be based on cumulative Net Sales from the start of a Calendar Year and reset on an annual basis.

For the avoidance of doubt, no royalties shall be due or payable on samples of Licensed Product or clinical trial materials or other transfers or dispositions of the

Licensed Product for charitable, promotional, pre-clinical, clinical, manufacturing, testing or qualification, regulatory or governmental purposes.

(b) Sublicense Income for an [[***]] Licensed Product. In addition to the associated milestones and royalties outlined above, Bayer shall pay to Atara the following percentage of all Sublicense Income:

*(i)***[[***]] percent [[***]] if at the time of execution of the sublicense agreement the status of the project is [[***]]; or**

*(ii)***[[***]] percent [[***]] if [[***]].**

(c) Reduction in Royalties.

*(i)***No Valid, Practiced Claim. If, during the Royalty Term, in any particular country in the Territory, a Licensed Product is not covered or claimed by a Valid, Practiced Claim, then the royalties that would otherwise have been payable on Net Sales of such Licensed Product in such country under this Agreement shall be reduced by [[***]] percent [[***]] as from the first Quarter in which there is no Valid, Practiced Claim. The calculation of the royalty reduction shall be conducted separately for each Licensed Product in each country.**

(ii) **Compulsory Licenses. [[***]].**

(iii) **Biosimilar Product. [[***]].**

(iv) **Third Party Technology. Subject to the last sentence of this Section 9.5.3.4, if during the term of this Agreement Atara or Bayer becomes aware of a Third Party Patent Right (excluding for clarity any Patent Rights controlled by MSK) and where Bayer reasonably determines, in the absence of a license to such Third Party Patent Right, such Third Party Patent Right would be infringed by the Exploitation of the Licensed Cell Therapeutic and / or Licensed Product (solely to the extent consisting of an Atara Cell Therapeutic), Bayer (itself or through any other Bayer Party) may obtain a license to such Third Party Patent Right in any country in the Territory. Atara agrees to fully co-operate with Bayer in any licensing of such rights by Bayer, as Bayer may reasonably request. In the event that Bayer pays any [[***]] in consideration solely for a license to such Third Party Patent Right for the Exploitation of the Licensed Cell Therapeutic and / or Licensed Product (solely to the extent consisting of an Atara Cell Therapeutic) (subject to the limitation specified in sentence 1 of this Section 9.5.3.4), as applicable, [[***]]payable by Bayer to Atara pursuant to Section 9.5.1 shall be reduced by [[***]] percent [[***]] of the amounts actually paid to such Third Party in such country as consideration solely for any such license to such Third Party Patent Rights for such purpose.**

*(v)***For clarity, Atara shall be solely responsible to cover any third party royalty obligations that Atara may have under the Existing Agreements in relation to this license.**

(d) Notwithstanding anything to the contrary in this Agreement, in no event shall the royalties payable to Atara under Section 9.5.1 be reduced to less than:

*(i)***[[***]]**

(e) Royalty Reporting. Starting from the date of First Commercial Sale of the Licensed Product(s) in any country, Bayer shall submit within [[***]] days after the end of each Quarter a good faith, non-binding, preliminary indication of Net Sales achieved within the previous Quarter (such preliminary indication not including any further breakdown, e.g., into countries, Licensed Products). Within [[***]] days of the end of each Quarter, Bayer shall prepare and deliver to Atara a written statement setting forth:

(i) **Net Sales for that Quarter on a Licensed Product-by-Licensed Product and country-by-country basis;**

*(ii)***[[***]]; and**

(iii) **[[***]];**

*(iv)***[[***]]; and**

(v) **the associated royalties due to Atara.**

Following Atara's receipt of such quarterly statement, Atara shall deliver to Bayer an invoice for the royalties due to Atara, and upon Bayer's receipt of such invoice, Bayer shall make the associated royalty payments in accordance with Section 9.6.2.

1.183 ***Payments.***

(a) Currency. All payments under this Agreement will be made in U.S. dollars. Where the payments due are calculated based on a currency other than U.S. dollars, the amount due will be converted to U.S. dollars using the average quarter to date exchange rate for the applicable quarter as consistently applied per Bayer's internal accounting and reporting process.

(b) Payment Date. The License Upfront Payment, the Reimbursement Upfront Payment, any and all royalties owing from Bayer to Atara under Section 9.5 and the payments owing from Bayer to Atara under Section 9.3, shall be paid by Bayer to Atara within [[***]] days after receipt of invoice, and the milestone payments and any other payment by Bayer shall be made within [[***]] days after receipt of invoice (each a "Payment Date").

(c) All payments due to Atara under this Agreement shall be paid upon the receipt of a respective invoice in U.S. dollars by wire transfer to the following bank account, or to such other bank account specified, at least [[***]] Business Days prior to the applicable Payment Date, in writing by Atara to Bayer:

Account Holder: [[***]]

Bank Name:	[[***]]
Bank Address, City, and State:	[[***]]
Account No.:	[[***]]
Bank Code:	[[***]]
SWIFT (BIC):	[[***]]
Routing Transit Number ABA:	[[***]]

Each invoice for payments shall be sent to:

[[***]]

mentioning such other information required and as may be amended and / or provided by Bayer to Atara from time to time.

Alternatively, each invoice for payments mentioning the aforementioned address and reference may be sent electronically in portable document format (pdf) via email without electronic signature ("pdf-invoicing"), to

[[***]]

thus replacing a corresponding paper form.

(d) Late Payments. All payments not made by [[***]] days after the respective Payment Date set out in this Agreement shall be subject to Late Payment interest at the United States Secured Overnight Financing Rate (SOFR), currently published on Bloomberg screen <SOFRRATE Index>, fixed [[***]] Business Days prior to the respective Payment Date and reset to the prevailing [[***]] month SOFR at monthly intervals thereafter, plus a premium of [[***]] (or the maximum applicable legal rate of interest if lower). Interest shall be calculated based on the actual number of days in the interest period divided by 360 and shall be calculated from the respective Payment Date (inclusive) until the date of payment (exclusive).

1.184 ***Taxes.***

(a) All agreed consideration is exclusive of Value Added TAX ("VAT"). If legally applicable, VAT will be invoiced and has to be paid additionally after receipt of a proper invoice, which meets all legal requirements according to the applicable VAT-law.

(b) Any party required to make a payment pursuant to this Agreement shall be entitled to deduct and withhold from the amount payable the tax for which paying party on behalf of payee is liable under any provisions of tax law. If the withholding tax rate is reduced according to the regulations in the Double Tax Treaty no deduction shall be made or a reduced amount shall be deducted only if paying party is timely furnished with necessary documents by payee issued from the relevant tax authority, certifying that the payment is exempt from tax or subject to a reduced tax rate. Except as otherwise provided in Section 9.6.3, any withheld tax shall be treated as having been paid by paying party to payee for all purposes of this Agreement. Paying party shall timely forward the tax receipts

certifying the payments of withholding tax on behalf of payee. In case paying party must pay, but cannot deduct the withholding tax due to fulfillment and completion of payment obligation by settlement or set-off, payee will pay the withholding tax to the paying party separately. If paying party failed to deduct withholding tax but is still required by tax law to pay withholding tax on account of payee to the tax authorities, payee shall assist paying party with regard to all procedures required in order to obtain reimbursement by tax authorities or, in case tax authorities will not reimburse withholding tax to paying party, payee will immediately refund the tax amount.

(c) Notwithstanding the foregoing, if (a) any party redomiciles or assigns its rights or obligations under this Agreement, (b) as a result of such redomiciliation or assignment, such Party (or its assignee) is required by Law to withhold taxes, or such redomiciliation or assignment results in the imposition of indirect taxes that were not otherwise applicable, from or in respect of any amount payable from such party to the other party under this Agreement, (c) the other Party is despite reasonable efforts not able to obtain an exemption or reduction from such additional tax; and (d) such withholding taxes or indirect taxes which cannot be exempted from tax by the other Party with reasonable efforts exceed the amount of withholding taxes or indirect taxes that would have been applicable had such redomiciliation or assignment not occurred, then any such amount payable shall be increased to take into account such withholding taxes or indirect taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable) and / or paying such indirect taxes, as the case may be, the payee party (or its assignee) receives an amount equal to the sum it would have received had no such increased withholding been made and no such Indirect Taxes had been imposed. The obligation to pay additional amounts pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax or indirect taxes would not have been imposed but for the assignment by the payee party of its rights or obligations under this Agreement or the redomiciliation of such payee party outside of the United States.

BOOKS, RECORDS, AUDIT

1.185 ***Records. Bayer shall keep, and shall procure that all Bayer Parties keep, true and accurate records and books of account containing all data necessary for the calculation of the amounts payable by it to Atara pursuant to this Agreement. Those records and books of account shall be kept for***

(i) with respect to Licensed Products that are covered by Licensed Patents under the MSK MSLN License and/or that are containing, derived from or made using BioVec Products (as such term is defined in the BioVec Upstream License), [[***]] years;

(ii) with respect to other Licensed Products than those listed under a) above, if they are covered by Licensed Patents under the NIH Upstream License, [[***]] years;

(iii) with respect to other Licensed Products than those listed under a) and b) above, if they are covered by Licensed Patents under the MSK PD1-DNR License and/or MSK CAR-T License, [[***]] years; and

(iv) with respect to other Licensed Products than those listed under a), b) and c) above, [[***]] years,

in each case following the end of the period to which they relate.

1.186 ***Audits. To validate Bayer's compliance with its obligations under or in connection with this Agreement, Atara may, during the course of this Agreement and for [[***]] year after termination of this Agreement, appoint an independent certified public accountant, at Atara's expense (except as otherwise contemplated below), to carry out an audit of Bayer's records from time to time on behalf of Atara. The auditors selected by Atara shall be subject to acceptance by Bayer, such acceptance not to be unreasonably withheld or delayed. Any such audit shall be conducted pursuant to the following terms and conditions:***

(a) Any such audits shall be conducted during regular business hours at Bayer's premises upon [[***]] days' prior written notice by Atara and shall not interfere unreasonably with the Bayer's business activities;

(b) The auditor may inspect records for up to [[***]] years after the end of the period to which they pertain;

(c) Audits may not take place more than [[***]] per Calendar Year and no period may be audited more than [[***]];

(d) Prior to the audit taking place, auditor shall undertake to Bayer that they shall keep all information confidential and shall not disclose any information to Atara (except as set forth in Section 10.2.5 below) or any Third Party, and shall only use the same for the purpose of calculations which they need to perform hereunder;

(e) Details of the auditor's findings (including, for the avoidance of doubt, monetary values and supporting calculations) shall not be shared with Atara except in the form of a summary report (and, in any event), the summary report shall be communicated to Bayer before being shared with Atara and Bayer shall be given a period of [[***]] Business Days to review and respond to the auditor's findings before the summary report may be provided to Atara (such reports to include Bayer's response to the findings);

(f) The auditor shall not be permitted to include any extrapolation calculations in their calculation of amounts allegedly underpaid to Atara;

(g) If an audit reveals that Bayer has underpaid royalties due, Atara may invoice Bayer for the underpaid amount;

(h) If an audit reveals an underpayment in excess of [[***]] percent [[***]] of the fees for the period subject to review by Atara, then Bayer shall pay the reasonable costs of the auditors within [[***]] days of Atara's receipt of the summary report in Section 10.2.5

notifying Bayer that the audit has been completed; for clarity, any underpayment shall be subject to Late Payment interest in accordance with Section 9.6.4; and

(i) If an audit reveals that Bayer has overpaid any royalties (the amount of each such overpayment, an "Overpayment Amount"), then, as may be requested by Bayer, (i) the Overpayment Amount will be credited against any future amounts payable to Atara by any Bayer Party, or (ii) Atara shall reimburse Bayer for such Overpayment Amount (or any portion thereof that has not been credited as set out in the foregoing clause within [[***]] days after the date such auditor reveals to any Bayer Party, or any Bayer Party reveals to Atara, such Overpayment Amount; for clarity, no interest shall become due on the Overpayment Amount from the date such payment was received by Atara until the due date after the overpayment was revealed.

INTELLECTUAL PROPERTY

1.187 ***Inventorship. Notwithstanding the provisions of Section 21.2, inventorship of any inventions created, generated, invented, discovered or conceived by, or on behalf of, a Party or any of its Affiliates, whether solely or jointly with any Third Party (or with the other Party or any of its Affiliates), in the course of the Collaboration Activities shall be determined by application of United States patent law pertaining to inventorship.***

1.188 ***Ownership.***

(a) Intellectual Property owned by Atara.

(i) **As between the Parties, Atara shall retain all right, title and interest in and to, and shall [[***]] own, [[***]] Licensed Technology (including [[***)] Atara Results) with the exception of [[***]] Results.**

*(ii)***No right or license is granted to Bayer hereunder with respect to any Licensed Technology, other than the licenses and rights granted to Bayer pursuant to Section 2.1.**

(b) Intellectual Property owned by Bayer.

*(i)***As between the Parties, Bayer will retain all right, title and interest in and to, and shall [[***]] own, [[***]]Bayer Results, Joint Results, Bayer Background Technology and Bayer Background Improvements.**

*(ii)***To the extent any copyrights constituting Bayer Background Improvements generated in whole or in part by Atara or any Joint Results, cannot be assigned by Atara to Bayer under applicable Law, Atara hereby grants Bayer an exclusive, irrevocable, perpetual, fully paid-up, royalty-free, world-wide license, with the right to grant sublicenses, to Exploit such copyrights and Joint Results for any and all purposes.**

*(iii)***No right or license is granted to Atara hereunder with respect to any Bayer Results, Bayer Background Technology, Bayer Background Improvements other than the licenses and rights granted to Atara pursuant to Article 2.**

(iv) **For clarity, as between the Parties, Bayer shall [[***]] own all intellectual property rights conceived and reduced to practice in the conduct of Bayer's activities [[***]] in exercise of the licenses granted by Atara to Bayer under this Agreement (such intellectual property rights, the "Bayer Improvement IP") and Bayer may file, prosecute, maintain and enforce Patent Rights on such Bayer Improvement IP as it deems appropriate.**

(c) Cooperation and Support. If and as may be reasonably requested by the other Party, each Party shall (and shall, as applicable, cause each of its employees, officers, directors, consultants or contractors to) duly execute and deliver (or cause to be duly executed and delivered) such agreements and other documents, including assignment agreements, and take such further actions (or cause such further actions to be taken), to make such assignment(s) as may be reasonably necessary or desirable to effect the ownership rights set out in this Section 11.2 and to evidence, confirm, record and perfect any such assignment(s).

1.189 ***Each Party will notify the other Party promptly in writing of any Result that is or might in its reasonable assessment be patentable (any such Result an "Invention") and shall, upon request of the other Party, provide the other Party with a Complete Invention Disclosure within a period of [[***]] days.***

1.190 ***Prosecution and Enforcement of Bayer Results and Bayer Background Improvements. Bayer has the exclusive right but no obligation to file, prosecute, maintain and enforce, in its own name, at its sole discretion and expense patent applications or other intellectual property rights on Bayer Background Improvements and Bayer Results in or for any country. Atara will, at Bayer's request, provide and execute all necessary documents including declarations/assignments and cooperate with Bayer, as reasonably required, to enable Bayer to conduct the drafting, filing and prosecution of such applications and to defend and enforce such rights.***

1.191 ***Filing, Prosecution and Maintenance of Joint Results Patents.***

(a) Bayer shall have the first right, but not the obligation, to prepare, file, prosecute and maintain the Joint Results Patents worldwide. Bayer shall keep Atara reasonably informed of all material steps with regard to the preparation, filing, prosecution and maintenance of the Joint Results Patents, including by providing Atara with a copy of material communications to and from any patent authority in the Territory regarding such Joint Results Patents, and Atara shall be copied on all material correspondence with Bayer's patent counsel with respect thereto. Bayer shall provide Atara drafts of any material filings or responses to be made to such patent authorities in the Territory in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Atara to review and comment thereon, and Bayer shall consider in good faith and discuss Atara's requests and suggestions with respect to Bayer's drafts and with

respect to strategies for filing and prosecuting the Joint Results Patents. Bayer shall consult with Atara reasonably prior to (but at least [[***]] days prior to) taking or failing to take any substantive action (including making any filings) with respect to the Joint Results Patents, including any action that would materially affect the scope or validity of rights under any patent applications or patents with the Joint Results Patents (such as substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional patent application, abandoning any patent or not filing or perfecting the filing of any patent application in any country). If Bayer decides not to prepare, file, prosecute or maintain a Joint Results Patent in a country in the Territory, Bayer shall provide reasonable prior written notice to Atara of such intention (which notice shall, in any event, be given no later than [[***]] days prior to the next deadline for any action that may be taken with respect to such Patent Right in such country), Atara shall thereupon have the option, in its sole discretion to assume the control and direction of the preparation, filing, prosecution and maintenance of such Joint Results Patent. Upon Atara's written exercise of such option, Atara shall assume the responsibility and control for the preparation, filing, prosecution and maintenance of such Joint Results Patent. In such event, Bayer shall promptly provide Atara with the appropriate documents for such transfer of responsibility and control and reasonably cooperate with Atara in such country, including by (i) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to enable Atara to apply for and to prosecute the Joint Results Patents in the Territory, and (ii) promptly informing Atara of any matters coming to Bayer's attention that may materially affect the preparation, filing, prosecution or maintenance of any such Joint Results Patent. The Parties shall [[***]] costs associated with filing and prosecuting the Joint Results Patents.

1.192 ***Filing, Prosecution and Maintenance of Licensed Patents.***

(a) Atara shall be responsible, and [[***]] to file, prosecute and maintain the Licensed Patent Rights, through a qualified and recognized patent counsel, at least in the countries listed in Exhibit 11.6.1, and shall [[***]]. Atara shall inform Bayer of any materially relevant communication with patent offices relating to the filing, prosecution or maintenance of such Licensed Patent Rights. Furthermore, Atara shall provide Bayer with copies of any materially relevant documents or correspondence with patent offices or any other documents which may be important for any action to be taken in a timely manner and no less than [[***]] days prior to any relevant deadline, provided such time is available. Bayer shall communicate its comments on the same to Atara on the earlier of: [[***]] days from the date the information was received by Bayer; and no less than [[***]] days before the deadline, or intended deadline, for the action to be taken, provided that such period is available, and Atara shall consider in good faith the comments provided by Bayer.

(b) If Atara determines that it is not commercially reasonable to file, nationalize (if applicable) or further prosecute a Licensed Patent Right in any country listed in Exhibit 11.6.1, Atara shall provide reasonable advance written notice ("Cessation Notice") to Bayer of such determination (which notice shall, in any event, be given no later than [[***]] days prior to the next deadline for any action that may be taken with respect to such Licensed Patent Right in such country). Upon receipt of such notice, Bayer may

object to such determination within [[***]] days and request that Atara continue filing or prosecuting such Licensed Patent Right. If the Parties cannot agree upon whether Atara will or will not continue to file or prosecute such Licensed Patent Right, such dispute will be referred to the [[***]] for dispute resolution in accordance with Section 20.1. During the dispute resolution process, Atara will continue to file and / or prosecute, as applicable, such Licensed Patent Right at Atara's cost. If, following dispute resolution in accordance with Section 20.1, the Parties determine that Atara's decision was appropriate, Bayer will [[***]] with the filing and / or prosecution of such Licensed Patent Right following Atara's delivery of the applicable Cessation Notice to Bayer.

(c) The Parties acknowledge and agree that this Section 11.6 is subject to the terms and conditions of the Existing Agreements, but solely with respect to those Patent Rights within the Licensed Patents Rights that are owned by MSK or NIH and licensed to Atara under the Existing Agreements.

1.193 ***Patent Enforcement.***

(a) Notice. If any Licensed Patent Right is or might be infringed by a Third Party making, using or selling a Competing Product in the Field (each a "Field Infringement"), the Party first having knowledge thereof shall promptly notify the other Party in writing. Such notice shall set forth the facts of the Field Infringement in reasonable detail.

(b) Enforcement.

(i) **Atara shall have the first right (but not the obligation), by counsel of its own choice and at its sole expense, to institute, prosecute and control the enforcement or defense of Licensed Patent Rights, except that, subject to Section 2.1.3 of this Agreement, Bayer shall have the first right (but not the obligation), by counsel of its own choice and at its sole expense, to institute, prosecute and control the enforcement of any Licensed Patent Rights within the Exclusive Technology against any Field Infringements. Prior to undertaking any such action to enforce or defend such Licensed Patents Rights, the Party controlling the suit or action ("Prosecuting Party") shall notify the other Party in writing. If the Prosecuting Party requests that the other Party join any such action, the other Party shall do so and the other Party hereby agrees that counsel for the Prosecuting Party shall also represent the other Party in such action. The other Party shall have the right, at its own expense, to also be represented in any action by counsel of its own choice. For the avoidance of doubt, should the other Party partake in any such action brought by the Prosecuting Party, either at the Prosecuting Party's request or otherwise, the Prosecuting Party shall retain control of the proceeding and shall have [[***]]related thereto.**

(ii) **In the event that the Party with the first right to enforce determines not to make use of its right to institute an action or proceeding or otherwise take appropriate action to enforce or defend Licensed Patent Rights, then such Party shall provide written notice to the other Party that it declines such right as to such activity as soon as reasonably practicable, but in no event later than [[***]] days**

after notice by the other Party requesting action, or within [[***]] days prior to any deadline associated with the defense or enforcement of the Licensed Patent Rights (which deadline has been previously communicated to the other Party), and after receiving such notice, subject to Section 2.1.3 of this Agreement, the other Party shall have the right (but not the obligation) to institute and / or prosecute and control such an action or proceeding in its name with respect to such enforcement or defense at its sole expense and by counsel of its own choice, and the non-Prosecuting Party shall have the right to be represented in any such action by counsel of its own choice and at its own expense. The Parties shall reasonably cooperate with each other in the planning and execution of any such action to enforce or defend such Licensed Patent Rights and shall [[***]].

(iii) **The Parties agree to cooperate fully in any action or proceeding for a Field Infringement, as applicable, pursuant to Sections 11.7.2.1 or 11.7.2.2. If a Party brings such an action or proceeding, such Party shall (a) keep the other Party reasonably informed of all material steps proposed to be taken, and provide copies of all material documents filed or received (to the extent permitted), in connection with the Licensed Patent Rights, as applicable, in such action or proceeding, and (b) consider in good faith any comments from the non-enforcing Party with respect thereto. At the request of the Party bringing such action or proceeding, the other Party shall, where necessary, furnish a power of attorney solely for such purpose or shall join in, or be named as a necessary party to, such action or proceeding. Bayer shall not settle any action or proceeding in accordance with Sections 11.7.2.1 and 11.7.2.2 with respect to a Field Infringement without the prior written approval of Atara, not to be unreasonably withheld, conditioned or delayed; provided, however, in all cases, Bayer shall not have the right to settle such action or proceeding in a manner that involves an admission of invalidity or unenforceability with respect to any Licensed Patent Rights, without the prior written consent of Atara, such consent to be granted or withheld in Atara's sole discretion. Without limiting the foregoing, if either Party initiates an action or proceeding pursuant to Sections 11.7.2.1 or 11.7.2.2, such Party shall provide the other Party with copies of all pleadings and other documents filed with the court.**

(iv) **All monies recovered upon the final judgment or settlement of any such suit or action to enforce the Licensed Patent Rights against a Field Infringement in the Field in the Territory shall be applied in the following order of priority: (x) first, the Party bringing suit or action shall be reimbursed for all costs and expenses (including reasonable attorney's fees and costs) incurred in connection with such suit or action, then to the costs and expenses (if any) of the other Party; and (y) thereafter, any remainder shall be shared as follows: [[***]] to Bayer and [[***]] to Atara.**

(c) Enforcement Outside Scope of Exclusive License. For the avoidance of doubt, Atara shall have the right (but not the obligation), at its sole expense and sole discretion, to control the enforcement or defense of the Licensed Patent Rights to abate any infringement other than a Field Infringement. Atara shall, however, in any such action coordinate and reasonably cooperate with Bayer with the intent to ensure that any position taken, and / or

arguments made, by Atara (e.g., claim constructions) do not adversely impact any of the Licensed Patent Rights or any of Bayer's rights or licenses hereunder.

(d) Patent Challenge. To the extent permitted by Laws on a country-by-country basis, Bayer agrees (i) not to challenge the validity or enforceability of any claim within the Licensed Patent Rights that are subject to the MSK Upstream Licenses, (ii) [[***]].

1.194 ***Defense of Third Party Claims. If a Party becomes aware of any actual or potential claim that the Exploitation of any Licensed Cell Therapeutic or Licensed Product or any other use by any person of Licensed Technology infringes the intellectual property rights of any Third Party, such Party shall promptly notify the other Party. (i) Atara shall not acknowledge to a Third Party the validity of any such allegation or admit liability without the prior written consent of Bayer, and (ii) Bayer shall not acknowledge to a Third Party the validity of any such allegation or admit liability without the prior written consent of Atara, in each case (i) and (ii), such consent not to be unreasonably withheld or delayed. Bayer and Atara shall each keep the other advised of all material developments in the conduct of any proceedings in defending any claim of such alleged infringement or misappropriation and shall cooperate with the other in the conduct of such defense. In no event may either Party settle any such infringement or misappropriation claim in a manner that would limit the rights of the other Party or impose any obligation on the other Party, without such other Party's prior written consent, such consent not to be unreasonably withheld or delayed. For clarity, this Section 11.8 is subject to Article 16.***

1.195 ***Product Marks. Bayer shall be responsible for the selection, registration and maintenance of all Product Marks, such Product Marks to be filed and maintained in Bayer's sole discretion. Bayer shall own and Control such Product Marks and pay all relevant costs with respect thereto.***

1.196 ***Bayer Marks. Atara hereby recognizes and acknowledges the exclusive ownership by Bayer of the Bayer Marks.***

1.197 ***Cooperation. The Parties shall reasonably cooperate with each other in connection with the matters covered by this Article 11, if and as may be reasonably requested by the other Party from time to time, and each Party shall bear all of its own related costs and expenses incurred in connection therewith.***

CONFIDENTIALITY

1.198 ***Definition.***

(a) As used herein, "Confidential Information" means all confidential or proprietary information disclosed by or on behalf of one Party or its Affiliates (such Party together with its Affiliates the "Disclosing Party") to the other Party or its Affiliates (such Party together with its Affiliates, the "Receiving Party") pursuant to this Agreement, in written, graphical, physical, electronic, oral or any other form. For the avoidance of doubt, Bayer's Confidential Information includes the royalty reports provided by Bayer or non-public results of any Clinical Trial sponsored by Bayer with respect to any Licensed Product as well as any Bayer Background Technology, Bayer Results and Bayer

Background Improvements, and Atara's Confidential Information includes any and all Licensed Know How.

(b) Further, the terms and conditions of this Agreement shall be deemed both Parties' Confidential Information hereunder and, with regard thereto, both Parties shall be subject to the obligations of confidentiality and non-use as per Section 12.2.

(c) Confidential Information does not include information which:

(i) is at the time of disclosure part of the public domain or becomes thereafter part of the public domain other than by an unauthorized disclosure of the Receiving Party. For the sake of clarity, information shall not be deemed to be in, or have come into, the public domain merely because any part of such information is embodied in general information which is or becomes publicly known or because individual features, components or combinations thereof are or become publicly known.

(ii) the Receiving Party can prove to have obtained from a Third Party prior to or after its disclosure by the Disclosing Party; provided that such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party under an obligation of confidentiality; and / or

(iii) information which the Receiving Party can prove was developed by or on behalf of it independently of the Confidential Information provided by the Disclosing Party.

1.199 ***Protection of Disclosing Party's Confidential Information.***

(a) Obligation of Confidentiality and Non-Use. Each Party agrees, with regard to Confidential Information received from the Disclosing Party, that during the term of this Agreement and for a period [[***]] years thereafter:

(i) it shall keep the Confidential Information strictly confidential and reasonably protected against disclosure as further described under Section 12.2.2 below;

(ii) it shall not use the Confidential Information, for any purposes other than those expressly permitted under this Agreement including, with regard to each Party, exercise of the rights and licenses granted to such Party pursuant to Article 2; and

(iii) it shall not disclose Confidential Information to any Third Party other than as permitted by Section 12.2.3.

(b) Information Security Obligations.

(i) **Each Party shall adopt technical and organizational measures to guarantee reasonable protection of the other Party's Confidential Information, including the measures listed in Exhibit 12.2.2.1.**

(ii) **Each Party may audit the other Party's technical and organizational measures. For this purpose, each Party shall have the right, upon [[***]] Business Days' prior notice and during regular business hours, to:**

1) request information from the other Party (self-reporting);

2) cause a personal on-site inspection of the other Party, by a qualified Third Party (on-site audit). For such on-site audit, the audited Party shall grant the auditing Party access to, in particular, the data processing systems, files and documents pertaining to or containing Confidential Information of the auditing Party; and / or

3) interview relevant personnel, provided that such rights may not be exercised in a manner that interferes with the normal operations and activities of the audited Party's personnel.

The audited Party shall and shall cause its personnel to cooperate with any such activities. In particular, it shall immediately make available to the auditing Party all information and certifications that are necessary for the performance of the information security control.

(c) Exceptions from the Obligation of Confidentiality and Non-Use. A Receiving Party may disclose Confidential Information disclosed to it as follows:

1) Confidential Information (including for clarity the terms of this Agreement) may be disclosed to the following persons and entities if such have a need to know and are bound by an obligation (contractual, fiduciary or otherwise) of confidentiality, non-use and non-disclosure at least as restrictive as set forth herein: (x) the Receiving Party's officers, directors and employees, (y) any Third Party to the extent reasonably necessary or appropriate to perform the Receiving Party's rights and / or obligations under this Agreement, which includes, with regard to each Party, actual or potential (A) in the case of Atara with respect to Licensed Know How, licensees, and (B) in the case of both Parties, Sublicensees, investigators, distributors, co-promoters, co-marketers, suppliers, contractors, consultants, insurers, service providers and other similar persons and entities and (z) potential investors, investment bankers, merger partners or acquirors of a Party or substantially all of its assets referring to the Licensed Cell Therapeutic(s) and any Licensed Products.

2) Each Receiving Party may also disclose Confidential Information disclosed to it to Regulatory Authorities or other governmental authorities in order to obtain, maintain or defend Patent Rights or seek or obtain approval to conduct Clinical Trials, gain Regulatory Approval or Pricing Approval with respect to a Licensed Product or otherwise Exploit a Licensed Cell Therapeutic and / or Licensed Product;

3) Confidential Information may also be disclosed if and only to the extent such disclosure is required by (x) Laws, (y) Securities Exchange Rules, or (z) a validly issued request for information from a Regulatory Authority (including, for the sake of clarity, any governmental authority); provided that promptly, however, if reasonably possible, not later than [[***]] Business Days prior to any such disclosure, to the extent permitted by Laws, the Receiving Party shall notify the Disclosing Party and give reasonable opportunity to review and comment on the proposed disclosure and / or seek a protective order or other appropriate remedy and the Receiving Party shall consider in good faith the comments provided by the Disclosing Party. In particular, the Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by either Party pursuant to Laws or Securities Exchange Rules; or

4) Any general, aggregate Confidential Information on the terms and conditions of this Agreement (including the Effective Date and maximum financial obligations) and on the collaboration of the Parties thereunder (including reach of Development milestones, estimated Development timelines) may be disclosed in a Voluntary Public Communication and / or Scientific Communication under the terms of Sections 13.1 and 13.2 without any additional approvals under Article 12 being required.

To the fullest extent permitted by Laws and / or Securities Exchange Rules, the Receiving Party shall seek confidential treatment of any Confidential Information disclosed to it under this Section 12.2.3(ii) and (iii).

Subject, for clarity, to Section 12.1.3, the status of Confidential Information disclosed pursuant to this Section 12.2.3 shall remain Confidential Information for all other purposes of this Agreement.

1.200 ***Protection of Licensed Know How. Without limiting Atara's rights to the Licensed Know How, and Bayer's confidentiality obligations with respect thereto, during the term of this Agreement Atara shall keep the Licensed Know How confidential and shall not disclose such to any Third Party; provided that (i) Section 12.2 shall apply mutatis mutandis (where Atara shall be deemed the Receiving Party solely for such purpose), and (ii) Atara shall not be restricted in disclosing Licensed Know How to any Third Party licensee (a) outside the Field, (b) within the Field, (x) solely with respect to therapeutic, prophylactic, diagnostic, and other healthcare-related products or treatments that are not directed to Mesothelin, or (y) with Bayer's consent, and / or (c) in a country of the Territory in which the exclusive license granted to Bayer hereunder has expired or become non-exclusive, provided that such Third Party licensee is bound by a contractual obligation of confidentiality and non-use at least as restrictive as set forth in this Agreement. For clarity, Atara is responsible to ensure that its contractors, collaborators and other licensees will also be bound by substantially similar confidentiality obligations with respect to any Licensed Know How.***

1.201 ***Prior Non-Disclosure Agreement. As of the Effective Date, the terms of this Article 12 shall supersede any prior non-disclosure, secrecy or confidentiality agreement(s) between the Parties (and / or their Affiliates) dealing with the subject matter of this Agreement, including***

[[***]]. Any confidential information disclosed under any such prior agreement shall be deemed disclosed under this Agreement.

PUBLICATIONS, PUBLICITY, USE OF NAME

1.202 ***The Parties shall not make any Public Communication nor submit or issue any Scientific Communication unless expressly permitted by Section 13.2 below.***

1.203 ***Voluntary Public Communication and Scientific Communication.***

(a) By Atara. Atara may issue (i) a Voluntary Public Communication and / or (ii) a Scientific Communication, provided that any such Voluntary Public Communication and / or Scientific Communication shall be conditional upon Bayer's prior written consent subject to the procedure as per Section 13.2.3 below. To the extent MSK issues any Scientific Communication relating to the ATA2271 Phase 1 Clinical Trial sponsored by MSK without Bayer's prior written consent, such issuance shall not constitute a breach of this Section 13.2.1 by Atara, provided that Atara shall use reasonable efforts under the terms of the applicable MSK Upstream Licenses to cause MSK to comply with this Section 13.2.1.

(b) By Bayer. Bayer may issue (i) a Voluntary Public Communication and / or (ii) a Scientific Communication; provided that Bayer allows Atara to review and comment in line with Section 13.2.3 below.

(c) Good faith cooperation. Each Party shall send to the other Party any Voluntary Public Communication and / or Scientific Communication (i) in case of a Voluntary Public Communication in the form of a statement included in any quarterly or annual earnings statements, press releases or investor presentations at least [[***]] Business Days prior to its intended publication, (ii) in case of any other Voluntary Public Communication at least [[***]] Business Days prior to its intended publication and (iii) in case of a Scientific Communication at least [[***]] Business Days prior to its intended submission or publication. The Parties shall cooperate in good faith to address any comments, concerns or objections within the respective period.

(d) Re-use. Once approved as per Section 13.2.1 (in case of Atara) or aligned as per Section 13.2.2 (in case of Bayer), after such approved Voluntary Public Communication has been issued, presented, or otherwise made by a Party, the precise or substantially similar wording may be frequently re-issued by such Party unless (i) the content of such Voluntary Public Communication has become misleading or otherwise inadequate as to subsequent developments, or (ii) any subsequent Voluntary Public Communication referring to the subject-matter thereof has been issued in line with Section 13.2.1 (in case of Atara) or Section 13.2.2 (in case of Bayer), in which case only the later Voluntary Public Communication may be re-issued, or (iii) the Parties have expressly agreed that a certain Voluntary Public Communication should exclusively be issued on one or more defined occasions.

(e) Any modification, alteration, amendment or adjustment of a Voluntary Public Communication or Scientific Communication shall be deemed a new Voluntary Public

Communication or Scientific Communication for the purpose of Sections 13.1, 13.2.1 and 13.2.2.

(f) For the sake of clarity: Any Confidential Information included in any Voluntary Public Communication or Scientific Communication shall be subject to Article 12.

(g) Article 12 shall remain unaffected with regard to the disclosure of such Confidential Information for any other purposes.

1.204 ***Mandatory Public Communication. Either Party may issue a Mandatory Public Communication subject to [[***]].***

1.205 ***Use of Product Mark. Atara agrees not to use the Licensed Product's expected trade name or any other expected Product Mark in any Public Communication in any country of the Territory prior to the Licensed Product obtaining Marketing Approval in such country without Bayer's prior written consent, which consent may, for clarity, be withheld in Bayer's sole discretion.***

1.206 ***Media Inquiries. Atara shall promptly direct all inquiries received by Atara or any of its Affiliates from members of the media and related to the Development or Commercialization of the Licensed Cell Therapeutic(s) and / or any Licensed Product to Bayer for handling, unless such media inquiry can be adequately answered by a Voluntary Public Communication which has been approved by Bayer in which case Section 13.2.4 shall apply.***

1.207 ***Press Release . The Parties shall mutually agree upon a joint press release regarding this Agreement and either Party may make subsequent Voluntary Public Communication of the contents of such press release in accordance with Sections 13.2.4 – 13.2.6.***

1.208 ***Non-Use of MSK's Name. Bayer shall not use the names of MSK, including Memorial Sloan Kettering Cancer Center, Sloan Kettering Institute for Cancer Research, and Memorial Hospital for Cancer and Allied Diseases, nor any of their employees, nor any adaptation thereof, in any public announcements, publicity or advertising relating to this Agreement without prior written consent obtained from Atara or MSK, except as otherwise expressly permitted in the MSK Upstream Licenses.***

REPRESENTATIONS, WARRANTIES

1.209 ***Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that as of the Effective Date:***

(a) It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation;

(b) It has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement (including, with respect to Atara, to grant the rights and licenses (including any sublicenses) granted by Atara to Bayer pursuant to this Agreement);

(c) It is duly authorized to execute and deliver this Agreement, and the person or persons executing this Agreement on its behalf have been duly authorized to do so by all requisite corporate action; and

(d) This Agreement is legally binding upon it, enforceable in accordance with its terms.

1.210 ***Representations and Warranties by Atara. Atara hereby represents and warrants to Bayer that as of the Effective Date:***

(a) General.

(i) **The execution and delivery of this Agreement by Atara, the performance of Atara's obligations hereunder, including the rights and licenses (including any sublicenses) granted by Atara to Bayer pursuant to this Agreement (A) do not conflict with or violate any requirement of any Laws existing as of the Effective Date and (B) do not materially conflict with, breach or constitute a default under, or otherwise violate any contractual obligations of Atara or any of its Affiliates existing as of the Effective Date;**

(ii) **To Atara's Knowledge, Atara has provided Bayer with all material information relating to the Licensed Technology and Licensed Cell Therapeutics in Atara's' or any of its Affiliates' possession or control, including all material information regarding ongoing Clinical Trials, efficacy, side effects, injury, toxicity or sensitivity, reaction and incidents or severity thereof and any manufacturing issues;**

(iii) **To Atara's Knowledge, the documents delivered or made available by Atara to Bayer in connection with the transaction contemplated by this Agreement do not contain any untrue statement of a material fact nor omit to state a material fact necessary in order to make the statements contained therein not misleading; and Atara has not, up through and including the Effective Date, withheld from Bayer any material information concerning the Licensed Technology, the Licensed Cell Therapeutic, the Licensed Product or the transaction contemplated by this Agreement;**

(IV) **Atara and, to Atara's Knowledge, its collaborators (including MSK) have in the course of developing the Licensed Cell Therapeutics and / or Licensed Products, not conducted any Development activities (including any preclinical studies or Clinical Studies) in material violation of any Laws;**

(V) **With respect to each submission to a Regulatory Authority regarding the Licensed Cell Therapeutic and / or Licensed Product, to Atara's Knowledge, Atara and its collaborators (including MSK) have not made an untrue statement of a material fact or fraudulent statement to such Regulatory Authority or knowingly failed to disclose a material fact required to be disclosed to such Regulatory Authority; and**

*(VI)***Neither Atara nor any employee of Atara, or to Atara's Knowledge, subcontractor, collaborator or employee of a subcontractor or collaborator which has performed services with respect to the Licensed Cell Therapeutic and / or Licensed Product has been debarred by any Regulatory Authority (including the FDA pursuant to its authority under Sections 306(a) and (b) of FDC Act) or is the subject of any investigation or proceeding which may result in debarment by any Regulatory Authority.**

(b) Existing Agreements.

(i) **Atara has provided to Bayer a true and complete copy (subject to appropriate redactions) of each Existing Agreement;**

*(ii)***The Existing Agreements constitute the only agreements and understandings Atara or any of its Affiliates has entered into with respect to any of the Licensed Technology;**

*(iii)***To Atara's Knowledge, each Existing Agreement is valid, binding and enforceable according to its terms and Atara is not in breach of any Existing Agreement; and**

*(iv)***Atara has not received any notice of any continuing default, breach or violation under any Existing Agreement.**

(c) Licensed Technology.

*(I)***Exhibit 1.85 contains a correct and complete list of all Licensed Patent Rights as of the Effective Date, including the status (as of the Effective Date) of each such Licensed Patent Right. To Atara's Knowledge, all of the Licensed Patent Rights issued as of the Effective Date are valid and enforceable;**

(II) **Atara (A) Controls all right, title and interest in the Licensed Know How specified in Exhibit 1.84 and the Licensed Patent Rights listed in Exhibit 1.85 (for clarity, including all materials, documents and data generated within the ATA2271 clinical development), which includes the right to grant the rights and licenses specified herein to the full extent contemplated under this Agreement, subject to the retained rights and other limitations in the Existing Agreements, as disclosed in redacted version to Bayer prior to the Effective Date; and (B) is the sole and exclusive owner of the Licensed Technology, with the exception of those parts of the Licensed Technology described in Exhibit 14.2.3.2(B). To Atara's Knowledge, none of the Licensed Technology, nor any of Atara's right, title or interest therein or thereto, is subject to any lien, option or other contingent right, restriction or claim of ownership (or other right, title or interest) by any Third Party (subject to the Existing Agreements) or any other encumbrance;**

*(III)***Neither Atara nor any of its Affiliates has granted any license or other right, title or interest to any Third Party relating to any of the Licensed Technology,**

Licensed Cell Therapeutics and / or Licensed Products which would conflict with the rights granted to Bayer hereunder;

(IV) **To Atara´s Knowledge, there is and has been no actual, alleged or threatened infringement, misappropriation or other violation of Licensed Technology and there are no claims, judgments or settlements against, or amounts with respect thereto owed by, Atara or any of its Affiliates relating to any of the Licensed Technology, and no Licensed Technology is subject to any outstanding consent, settlement, decree, order, injunction, judgment, or ruling, including any that restricts or otherwise limits the use, ownership, validity, enforceability, disposition or other exploitation thereof;**

(V) **Neither Atara nor any of its Affiliates has received any written or, to Atara's Knowledge, any other communication from any Third Party, or is or was a party to any suit, action or other proceeding pursuant to which any Third Party is or was, (A) claiming that the practice or other use of the Licensed Technology or the Exploitation of the Atara Cell Therapeutics is or was infringing the patent rights, or misappropriating or otherwise violating any other intellectual property rights, of any Third Party (including in any demand letter to in-license any Third Party intellectual property), or (B) challenging the validity, enforceability, patentability, use or ownership of any of the Licensed Technology or with respect to the Atara Cell Therapeutics, including by making any adverse claim of ownership thereof or claiming joint ownership or that the Licensed Patent Rights are invalid or unenforceable (and, in each case (clauses (A) and (B)) to Atara's Knowledge, none of the foregoing have been threatened and there is no reasonable basis for any of the foregoing;**

(VI) **The Licensed Patent Rights are being equitably and diligently filed and prosecuted with the respective patent offices in accordance with all Laws and all applicable patent prosecution and maintenance fees with respect thereto have been timely paid;**

(VII) **To Atara's Knowledge, there are no facts or circumstances which cause it to believe or conclude that any Licensed Patent Right is or may be invalid or unenforceable;**

(VIII) **To Atara's Knowledge, [[***]] neither the manufacturing of Atara Cell Therapeutics nor the practice or other use of any Licensed Technology relating to CMC and manufacturing of Atara Cell Therapeutics and, to Atara's Knowledge, neither the other Exploitation of the Atara Cell Therapeutics nor the practice or other use of any other Licensed Technology in accordance with the licenses granted by Atara to Bayer under this Agreement is infringing, misappropriating or otherwise violating any Patent Right or Know How of any other person or entity; and**

(IX) **Neither Atara nor any of its Affiliates has entered into an agreement or other arrangement with any academic institution, research center or governmental**

authority (or any person working for or on behalf of any of the foregoing) and / or accepted any funding, facilities, personnel or other resources from any academic institution, research center or governmental authority with respect to the Development of any Licensed Technology or any Atara Cell Therapeutic, including in connection with the conception, invention, reduction to practice, development or other creation of any intellectual property relating to any or any intellectual property that is included in any Licensed Technology or Atara Cell Therapeutic, except for, and pursuant to, the Existing Agreements.

1.211 ***Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, COMMERCIALIZATION AND MANUFACTURE OF THE LICENSED CELL THERAPEUTIC AND / OR LICENSED PRODUCTS, OR THE OBTAINMENT OF MARKETING AUTHORIZATION OR PRICING APPROVAL IN ANY PARTICULAR COUNTRY, PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.***

ADDITIONAL COVENANTS

1.212 ***No Transfer of Rights. During the term of this Agreement, without Bayer's prior written consent, Atara shall not, and shall cause its Affiliates not to:***

(i) transfer by assignment or otherwise any of the Licensed Technology to any Third Party except in strict compliance with Section 21.5;

(ii) grant any lien, option or other contingent right, or any other encumbrance on the Licensed Technology, in each case, which would conflict with the rights and licenses granted to Bayer hereunder; nor

(iii) grant any right, title or interest to any Third Party relating to the Licensed Technology, or any Licensed Cell Therapeutic or Licensed Product, which would conflict with the rights and licenses granted to Bayer hereunder.

1.213 ***Existing Third Party Obligations.***

(a) Within [[***]] Business Days following the Effective Date, Atara shall provide to Bayer a true and complete unredacted copy of each Existing Agreement. During the term of this Agreement, Atara shall:

(i) keep Bayer reasonably informed of any material development pertaining to, including any request or proposal to amend or modify, an Existing Agreement, in each case that could reasonably be expected to adversely affect the rights and licenses granted to Bayer hereunder;

(ii) not amend, or waive any right under, any Existing Agreement (in each case where such amendment or waiver could reasonably be expected to

adversely affect the rights and licenses granted to Bayer hereunder) without the prior written consent of Bayer which consent shall not be unreasonably withheld or delayed;

(iii) maintain each Existing Agreement in full force and effect; and

(iv) perform its obligations thereunder, including any payment obligations due pursuant to any Existing Agreement.

(b) With respect to any breach or default under any Existing Agreement that if uncured would enable the other party(ies) to such Existing Agreement to render non-exclusive or terminate the licenses granted to Atara thereunder (which would in turn render non-exclusive or terminate or have any other detrimental impact on Bayer's interests with respect to the licenses granted to Bayer hereunder), Atara shall if notified of such breach or default or notified of the other party´s intention to notify:

(i) give prompt written notice thereof to Bayer;

(ii) cure such breach or default within the period of time as may be required pursuant to the applicable Existing Agreement; and

(iii) provide Bayer with written confirmation thereof.

In the event that Atara is unable to cure such breach or default within this required time period, Atara shall provide Bayer with prompt written notice thereof and, to the extent permitted under the applicable Existing Agreement, permit Bayer, in its sole discretion, to cure such breach or default within the relevant cure period on behalf of the Atara, if possible. All out-of-pocket sums expended by Bayer in the exercise of its rights under this section, and concomitant interest (at the rate set forth in Section 9.6.4) accruing shall be deducted by Bayer from any future sums due from Bayer to the Atara pursuant to this Agreement.

1.214 ***Non-Compete.***

(a) No Development or Commercialization of Competing Products. Except as permitted or required pursuant to terms of this Agreement, subject to Section 15.4, Atara covenants that neither it nor any of its Affiliates shall, during the term of this Agreement, perform, or actively and voluntarily participate or assist any Third Party in performing, (i) any Development with respect to, or Manufacture or Commercialization of any Competing Product; or (ii) any research program the goal of which is to identify Competing Products, in each case (i) and (ii) provided that the covenant not to Develop Competing Products, including with respect to [[***]] expires on [[***]].

(b) Development After [[***]]. Except as permitted or required pursuant to terms of this Agreement, subject to Section 15.4, Atara covenants that neither it nor any of its Affiliates shall, [[***]] of a Licensed Product in a [[***]], perform, or actively and voluntarily participate or assist any Third Party, in performing, any Development of a Competing Product entailing the use by Atara of employees of Atara who have been

involved in the Development of the Licensed Cell Therapeutic and / or Licensed Product, unless the Know How regarding the Licensed Cell Therapeutic and / or Licensed Product gained by such employees could not reasonably be used for the Development of the Competing Product.

(c) With regard to any country of the Territory in which any covenants contained in Sections 15.3.1 or 15.3.2 might violate the Laws, now or in the future, such covenants shall become null and void and of no effect, but only to the extent it violates the Laws of such country and provided, for clarity, that Sections 15.3.1 and 15.3.2 shall remain valid with regard to any other country of the Territory.

1.215 ***Transactions by Atara.***

(a) Notification Requirement. Notwithstanding Section 15.3, in the event that (i) Atara or (subject to Section 15.4.5) any of its Affiliates acquires, whether by merger, acquisition, asset purchase, or other similar transaction, a Third Party or any of its Affiliates (collectively, the "Acquired Affiliate") and, (ii) prior to the date of the consummation of the relevant transaction (the "Acquisition Date"), the Acquired Affiliate has been (either directly or through any Third Party) Exploiting one or more Competing Products in a way that would violate Section 15.3 if done so by Atara (the "Acquired Competing Products"), then Atara shall provide written notice of such Acquired Competing Products to Bayer within [[***]] days from the Acquisition Date ("Acquisition Notice Period").

(b) Election of Remedy. Prior to the end of the Acquisition Notice Period, Atara shall elect with regard to each Acquired Competing Product either to: (i) terminate, or cause the Acquired Affiliate to terminate, the Exploitation of the Acquired Competing Product in violation to Section 15.3 or (ii) divest, or cause the Acquired Affiliate to divest, whether by license or otherwise, such Acquired Competing Product.

(c) Termination of Acquired Competing Product. If Atara notifies Bayer about its intention to terminate an Acquired Competing Product according to Section 15.4.2(i), then Atara or its Acquired Affiliate shall (i) terminate the Exploitation of such Acquired Competing Product as promptly as reasonably possible with due regard for patient safety and the requirements of Laws; and (ii) confirm to Bayer in writing when such termination has been completed.

(d) Divestment of Acquired Competing Product. If Atara notifies Bayer about its intention to divest an Acquired Competing Product in accordance with Section 15.4.2(ii), then Atara or its Acquired Affiliate shall effect such divestment within [[***]] months of the Acquisition Date; provided, that such [[***]] months period shall be extended for an additional period not to exceed [[***]] days if necessary to obtain any merger clearance required to complete such divestiture. Atara shall keep Bayer reasonably informed of its efforts and progress in effecting such divestiture until it is completed. If Atara or its Acquired Affiliate effects such divestiture by way of one or more licenses or sublicenses, then Atara or its Acquired Affiliate shall be entitled to receive license fees, milestones and royalties on sales of any Acquired Competing Product so divested; provided that

neither Atara nor its Acquired Affiliate funds or continues to conduct development or commercialization of such Acquired Competing Product.

(e) Change of Control of Atara. If Atara enters into a transaction or series of transactions with a Third Party acquiror that constitutes a Change of Control of Atara [[***]] then the Third Party acquiror (and / or its affiliates other than Atara, which affiliates, together with the Third Party acquiror, shall be referred to as the "Acquiror Group") shall not be subject to Sections 15.3 or 15.4.1-15.4.4, provided that (i) no Licensed Technology (for clarity, neither any Exclusive Technology nor Non-Exclusive Technology) or Bayer Confidential Information is used by the Acquiror Group in connection with any Competing Product Exploited by the Acquiror Group, and (ii) the Acquiror Group implements reasonable measures to ensure that the personnel engaged in the development and / or commercialization of Licensed Cell Therapeutics and Licensed Products operate independently from the personnel engaged in the development and / or commercialization of the Competing Product(s).

1.216 ***Bayer Activities. Nothing in this Agreement shall be interpreted as prohibiting a Bayer Party from, independently or with a Third Party, directly or indirectly, including through any ownership interest, funding or conducting any activity that has as its goal or intent discovering, identifying or Exploiting a Competing Product or any other compound or product, provided that no Licensed Technology or Confidential Information of Atara and / or its Affiliates is used or accessed in connection with the foregoing activities outside the scope of the licenses and any other rights granted to Bayer under this Agreement.***

INDEMNIFICATION, LIABILITY, INSURANCE

1.217 ***Indemnification by Bayer. Bayer shall defend, indemnify and hold harmless***

(i) Atara, its Affiliates and their respective directors, officers, and employees; as well as

(ii) solely with respect to Licensed Product that are covered by Licensed Technology that is subject to MSK Upstream Licenses, MSK and its trustees, directors, officers, medical and professional staff, employees, students, and agents and their respective successors, heirs, and assigns; and

(iii) solely with respect to Licensed Product that are covered by Licensed Technology that is subject to the NIH Upstream License, NIH and its trustees, directors, officers, medical and professional staff, employees, students, and agents and their respective successors, heirs, and assigns,

(the "Atara Indemnified Parties") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Losses"), arising from or occurring as a result of a Third Party's claim (including any Third

Party product liability), action, suit, judgment or settlement to the extent such Losses are due to or based upon:

(a) the Exploitation of the Licensed Product;

(b) gross negligence, intentional wrongful acts or omissions or violations of Laws by a Bayer Party or their respective directors, officers or employees in connection with the Licensed Product; or

(c) breach by Bayer of any representation, warranty or covenant made by Bayer in this Agreement,

except, in each case, to the extent arising from or occurring as a result of (A) the gross negligence, intentional wrongful acts or omissions or violations of Laws by Atara, its Affiliates, Upstream Licensors or any of their respective directors, officers or employees; or (B) the breach by Atara of any representation, warranty or covenant made by it in this Agreement.

1.218 ***Indemnification by Atara. Atara shall defend, indemnify and hold harmless each Bayer Party and their respective directors, officers, and employees (the "Bayer Indemnified Parties") from and against all Losses arising from or occurring as a result of a Third Party's claim (including any Third Party product liability), action, suit, judgment or settlement to the extent such Losses are due to or based upon:***

(i) the ATA2271 Phase 1 Clinical Trial and any other Phase 1 Clinical Trial related to ATA2271;

(ii) gross negligence, intentional wrongful acts or omissions or violations of Laws or regulation by or of Atara, its Affiliates, Upstream Licensors or their respective directors, officers or employees in connection with the Licensed Product;

(iii) breach by Atara of any representation or warranty made by it in the Agreement; or

(iv) any conflict arising from the explicit apportionment of the Upfront License Payment set forth in Section 9.1,

except, in each case, to the extent arising from or occurring as a result of (A) the gross negligence, intentional wrongful acts or omissions or violations of Laws by a Bayer Party or any of their respective directors, officers or employees; or (B) the breach by Bayer of any representation, warranty or covenant made by Bayer in this Agreement.

1.219 ***Claims for Indemnification.***

(a) A person entitled to indemnification under Section 16.1 or 16.2 (an "Indemnified Party") shall give prompt written notification to the person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party.

(b) Within [[***]] days after receipt of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel of its choice. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense.

(c) The Party not controlling such defense may participate therein at its own expense.

(d) The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider in good faith reasonable recommendations made by the other Party with respect thereto.

(e) If the Indemnifying Party chooses to defend or prosecute any Third Party claim, the Indemnified Party that is a Party to this Agreement shall, and shall cause each of its Affiliates and each of their respective directors, officers, employees and agents to reasonably cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party claim, and making the Indemnified Party, its Affiliates and its and their respective directors, officers, employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided, and the Indemnifying Party shall reimburse the Indemnified Party for all of its related reasonable out-of-pocket expenses.

(f) The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party.

1.220 ***Limitation of Liability. EXCEPT IN CASES OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE OR OBLIGATED TO THE OTHER PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, OR LOST PROFITS, LOST REVENUE OR LOST GOODWILL, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCT LIABILITY OR OTHERWISE, EVEN IF INFORMED OF OR AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE, PROVIDED THAT THIS LIMITATION OF LIABILITY SHALL NOT APPLY (I) TO THE EXTENT THAT IT WOULD BE INVALID BY LAW, (II) FOR A MATERIAL BREACH OF ARTICLE 12 (CONFIDENTIALITY) AND / OR (III) TO CLAIMS ARISING IN CONNECTION WITH SECTIONS 16.1, 16.2 AND 16.3 (INDEMNIFICATION).***

1.221 ***Insurance.***

(a) Subject to the proceeding subsection, each Party, at its own expense, shall, during the term of this Agreement, at its sole cost, obtain, carry and keep in force a liability insurance covering such risks as are appropriate in accordance with sound business practice and the Parties' obligations under this Agreement.

(b) In lieu of the insurance coverage described in the preceding subsection, Bayer shall have the right to undertake self-insurance to cover its obligations hereunder, with financial protection comparable to that arranged by it for its own protection with regard to other products in its portfolio.

COMPLIANCE WITH LAWS

1.222 ***Compliance. Both Bayer and Atara shall perform, and shall procure that their respective Affiliates and Sublicensees perform, their obligations under this Agreement in accordance with the Law and accepted pharmaceutical industry business practices, including, if and to the extent applicable to such Party (or its Affiliates or Sublicensees, as applicable) or its (or their) activities hereunder, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), the Public Health Service Act (42 U.S.C. § 201 et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA or other applicable Regulatory Authority. Each Party shall promptly notify the other Party in writing of any written allegation received from a Third Party or Regulatory Authority of an alleged material deviation from applicable Laws with respect to activities under this Agreement. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate (or cause the other Party to violate), any Law.***

1.223 ***Export Controls. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Bayer or Atara from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental authority approval, without first obtaining the written consent to do so from the appropriate governmental authority.***

1.224 ***Marking of Licensed Products. With respect to Licensed Products that are subject to the MSK Upstream Licenses, to the extent required by Law, or if the failure to mark would reduce the rights of MSK or Atara to enforce such Licensed Patent Rights against infringers, Bayer shall mark, and shall cause its Affiliates and Sublicensees to mark, such Licensed Products (or the packaging thereof) with the appropriate Licensed Patent Rights.***

1.225 ***Data Privacy.***

(a) General aspects.

(i) **Each party shall comply with their respective obligations under applicable data privacy laws.**

(ii) **Data privacy related terms shall have the meaning as defined in Art. 4 General Data Protection Regulation EU 2016/679 (GDPR) if not otherwise defined in this Agreement.**

(iii) **The Parties acknowledge that they will need to process personal data of the respective other Party's employees ("Employee Data") for the purpose of executing this contract.**

(iv) **In the context of this Agreement, a Party may need to transfer human biological samples (including any derivatives or progeny thereof like cell lines) ("Human Samples") including information regarding the origin, pathology or integrity of such samples and/or other research related data (including information about health) on a one-person-level to the respective other Party. Such data, and/or the results of analyses of said human biological samples, may qualify as personal data (in this case: "Human Data"). For the avoidance of doubts, one-person-level data may qualify as personal data (if it falls under the definition of personal data in applicable data privacy law) but does not necessarily do so.**

(b) Privacy obligations of Disclosing Party.

(i) **Where a Party discloses Human Samples and/or Human Data to the respective other Party, the disclosing Party is responsible to ensure meeting all conditions that are legally required to allow this disclosure for purposes of this Agreement (including medical and diagnostic research and development purposes). This may include e.g. ensuring that respective data subjects have given and not withdrawn their consents, or anonymizing or de-identifying Human Samples and/or Human Data prior to disclosure (examples not exhaustive).**

(ii) **In case a transfer of Human Samples and/or Human Data from Bayer to Atara is required, the Parties hereby enter by reference the standard contractual clauses as published by the European Commission as Decision 2004/915/EC. Atara as data importer will process personal data in scope of the standard contractual clauses according to Annex A of the standard contractual clauses. Specifications required for annex B are as follows:**

A. Data subjects: Participants of clinical studies, donors of human samples

B. Purposes of transfer: Purposes as specified in the Agreement

C. Category of data: Human Samples and/or Human data collected as part of clinical studies or obtained for research purposes

D. Recipients: Atara

E. Sensitive data: Data about health, genetic data

F. Contact point for data protection inquiries:
Data importer: [[***]]
Data exporter: [[***]]

In the event that a change in applicable data protection law would require a different transfer mechanism than the standard contractual clauses as published by the European Commission as Decision 2004/915/EC in order to allow an export of personal data from Bayer to Atara, Bayer and Atara shall cooperate in good faith to implement such an alternative prior to the effective date of any such change.

(iii) **Each Parties confirms that at time of signature of this Agreement, it is not aware of any legal requirement that may hinder disclosing Human Samples and/or Human Data to the respective other Party as required to fulfill the obligations under this Agreement.**

(iv) **The Party disclosing Human Data to the other Party shall do so only encrypted or via secure communication channels.**

(c) Privacy obligations of Receiving Party.

(i) **The Party receiving Employee Data and Human Samples and/or Human Data from the respective other Party may only use those as required for purposes of this Agreement.**

(ii) **Receiving Party is responsible to meet applicable privacy Laws when using received Human Samples and/or Human Data; receiving Party is in this respect a data controller as defined in the GDPR.**

(iii) **Receiving Party shall refrain from any attempt to identify the donor and/or data subject of the Human Samples and/or Human Data. This includes that Human Samples and/or Human Data shall not be supplemented or combined with any information which de-facto allows for a re-identification.**

(iv) **Receiving Party shall implement appropriate technical and organizational measures to protect the Human Samples and/or Human Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected. This included restricting access to Human Samples and/or Human Data to a need-to-know level.**

(v) **Receiving Party shall notify the disclosing Party without undue delay in the event that receiving Party becomes aware of a breach of applicable data privacy laws in the context of activities related to the Agreement.**

TERM AND TERMINATION

1.226 ***Term. This Agreement shall commence on the Effective Date and shall end, on a Licensed Product-by-Licensed Product and country-by-country basis upon the earlier of (i) expiration of the Royalty Term applicable to such country, or (ii) any termination of this Agreement or parts thereof in accordance with Section 18.2 below.***

1.227 ***Termination.***

(a) Termination by Bayer. Bayer shall have the right to terminate this Agreement in whole or on a Licensed Product-by-Licensed Product and country-by-country (except in any of the Major Market countries) basis at any time after the Effective Date on at least [[***]] days prior written notice to Atara.

(b) Termination for Breach. Either Party shall be entitled to terminate this Agreement by written notice to the other with immediate effect if the other Party materially breaches any of its material obligations under this Agreement and, if such breach is curable within the aforesaid period, fails to cure such breach within [[***]] days following its receipt of written notice thereof from the terminating Party.

(c) Termination for Patent Challenge. If Bayer or [[***]] (a) commences or actively and voluntarily participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of any Licensed Patent Rights, or (b) actively and voluntarily assists any other party in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of any Licensed Patent Rights (each of (a) and (b), a "Patent Challenge"), then, to the extent permitted by Laws, Atara shall have the right, in its sole discretion, to give notice to Bayer that Atara may terminate this Agreement [[***]] days following such notice and, unless Bayer or such Bayer Party, as applicable, withdraws or causes to be withdrawn all such challenge(s) within such [[***]] day period, Atara shall have the right to (i) [[***]] terminate this Agreement by providing written notice thereof to Bayer or (ii) [[***]]. The foregoing right to terminate shall not apply with respect to any Patent Challenge where the Patent Challenge is made in defense of an assertion of the relevant Patent Right that is first brought by Atara against Bayer.

(d) Termination for Bankruptcy. To the extent permitted by Law, either Party may terminate this Agreement by written notice to the other with immediate effect if the other Party is compelled to file bankruptcy, or appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, or makes a general assignment for the benefit of creditors, in each case, where the relevant proceedings are not dismissed, discharged or stayed within [[***]] days after the filing thereof

1.228 ***Effect of Termination or Expiration of Agreement.***

(a) In case of any termination or expiration of this Agreement, all rights and obligations of the Parties shall cease immediately, unless otherwise indicated in this Agreement.

(b) Expiration or termination of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

(c) Upon termination or expiration of this Agreement, upon the request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or destroy the Disclosing Party's Confidential Information, including all copies thereof, except to the extent that retention of such Confidential Information is reasonably necessary for the Receiving Party to Exploit any continuing rights it may have and / or to fulfill its obligations contemplated herein, including its obligations of non-disclosure and non-use hereunder. The return and / or destruction of such Confidential Information as provided above shall not relieve the Receiving Party of its obligations under this Agreement. The provisions of this section shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the Receiving Party according to provisions of Law or the Receiving Party's internal policies and procedures.

(d) Program Transfer.

(i) **Upon termination of this Agreement in its entirety (i) [[***]] or (ii) [[***]], in each case (i) and (ii) at Atara's option, upon written notice submitted to Bayer no later than [[***]] days after the effective date of the termination, [[***]].**

(ii) **Upon agreement of a program transfer agreement or Atara's request for a Program Transfer, as applicable, in each case, pursuant to Section 18.3.4.1, Bayer will (in the case of a program transfer agreement, within the timelines agreed in such agreement, or otherwise as promptly as reasonably practicable), in each case to the extent legally possible without breaching any Laws (including on data privacy) or obligations towards Third Parties (including contractual obligations), make the following transfers to Atara ("Program Transfer"):**

1) Regulatory Documentation. [[***)].

2) Clinical Trials. [[***]].

3) Trademarks. [[***]].

4) Inventory. [[***]].

5) Licenses. [[***]]

6) Transition of Contracts. [[***]].

1.229 ***Additional Effects of Expiration. Upon expiration (but not early termination) of this Agreement in a particular country pursuant to Section 18.1, Bayer shall have a fully paid-up, perpetual, irrevocable [[***]] license (including the right to [[***]]) in the Field in such country under the Licensed Technology to Exploit the Licensed Cell Therapeutic(s) / Licensed Product(s).***

1.230 ***Bayer's Rights upon Atara's Bankruptcy.***

(a) All licenses granted under this Agreement shall be deemed licenses of rights to intellectual property for purposes of Section 365(n) of the U.S. Bankruptcy Code as it may be amended from time to time (the "U.S. Bankruptcy Code"). The Parties hereby agree that Bayer may fully exercise all of its rights and elections under the U.S. Bankruptcy Code.

(b) The Parties hereby agree that Bayer, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other Law outside the United States that provide similar protection for intellectual property rights. Atara (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) grants to Bayer and its Affiliates a right to obtain possession of and to benefit from a complete duplicate of (or complete access to, as appropriate) any Licensed Technology and all embodiments of the Licensed Technology held by Atara or such successors and assigns, or otherwise available to them, which, if not already in Bayer's possession, shall be promptly delivered to Bayer upon Bayer's written request. Embodiments of Licensed Technology includes all tangible, electronic or other embodiments of rights and licenses hereunder, including all Licensed Products, all Regulatory Documentation and rights of reference therein. Atara (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) shall not interfere with the exercise by Bayer or its Affiliates of rights and licenses to Licensed Technology and embodiments of Licensed Technology licensed hereunder in accordance with this Agreement and agrees to reasonably assist Bayer and its Affiliates to obtain the Licensed Technology and embodiments of Licensed Technology in the possession or control of Third Parties as reasonably necessary or desirable for Bayer or its Affiliates to exercise such rights and licenses in accordance with this Agreement (in each case to the extent Atara has such right under the agreement(s) with the applicable Third Parties). Whenever Atara (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) provides to Bayer, pursuant to this Section 18.5, any of the Licensed Technology and embodiments of Licensed Technology in accordance with this Agreement, Bayer shall have the right to perform the obligations of Atara hereunder with respect to such Licensed Technology and embodiments of Licensed Technology, but neither such provision nor such performance by Bayer shall release Atara (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) from liability

resulting from any rejection of the license or the failure to perform such obligations set forth in this Agreement.

1.231 ***Survival. The provisions of Sections 2.1.2, 2.1.3, 2.2.2, 2.2.3, 2.8, 3.3.4, 8.1 (solely with respect to units of Licensed Products administered or sold prior to the expiration or termination of this Agreement), 9.6.4 (solely with respect to payments that are accrued but unpaid at the time of expiration or termination, or otherwise to the extent applicable), 9.7, 11.2, 14.1-14.2 (solely with respect to claims arising from a breach of warranty, subject to applicable statute of limitation),14.3, 17.4, 18.3, 18.4, 18.5.1, 18.5.2 (if this Agreement is terminated by either Party under Section 18.2.4) and this 18.6 and Article 1, Article 10, Article 12, Article 16 (but not Section 16.5), Article 20 and Article 21 shall survive any termination or expiration of this Agreement.***

FORCE MAJEURE

1.232 ***Force Majeure. Neither Party shall be responsible or liable to the other Party for any failure to perform any of its obligations hereunder, if such failure results from circumstances beyond the control of such Party, including requisition by any governmental authority, the effect of any statute, ordinance or governmental order or regulation, wars, strikes, lockouts, riots, epidemic, pandemic, disease, an act of God, civil commotion, fire, earthquake, storm, failure of public utilities, common carriers or supplies, or any other circumstances, whether or not similar to the above causes and whether or not foreseeable ("Force Majeure"). The Parties shall use Commercially Reasonable Efforts to avoid or remove any such cause and shall resume performance under this Agreement as soon as feasible whenever such cause is removed; provided that the foregoing shall not be construed to require either Party to settle any dispute with any Third Party, to commence, continue or settle any litigation, or to incur any unusual or extraordinary expenses.***

1.233 ***Prompt Notification. The Party affected by the Force Majeure event shall upon its occurrence promptly give written notice to the other Party specifying the nature of the event and its anticipated duration.***

DISPUTE RESOLUTION

1.234 ***Dispute Resolution. If a dispute arises, other than a dispute governed by Section 3.7, each Party shall notify the other Party of the dispute and the issue shall be referred to each Party's Executive Sponsor who shall meet within [[***]] days (in person, by means of telephone conference, videoconference or other means of communications) and attempt in good faith to resolve such issue (subject only to, in the case of Atara, approval of its board of directors or, in the case of Bayer, approval of the applicable management board, if required). All such discussions shall be confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. Notwithstanding the foregoing, if such executives cannot resolve such matter within [[***]] days of the date such matter is first referred to them, then, either Party may pursue the remedies set forth in Sections 20.2 - 20.4.***

1.235 ***Arbitration . Subject to Sections 20.3 - 20.5 below, any dispute, which cannot be resolved pursuant to Section 20.1 above, shall be finally settled under the Rules of Arbitration***

of the International Chamber of Commerce (the "Rules") by a panel of three arbitrators appointed in accordance with the Rules, save that the third arbitrator, who will act as president of the arbitral tribunal, shall not be appointed by the International Court of Arbitration, but by the two arbitrators which have been appointed by either of the Parties in accordance with Article 12 para 4 of the Rules. The place of arbitration shall be New York and the language to be used in any such proceeding (and for all testimony, evidence and written documentation) shall be English. The IBA Rules on the Taking of Evidence in International Arbitration shall apply on any evidence to be taken up in the arbitration.

1.236 ***Disputes Related to Diligence. If Atara believes Bayer is in breach of its obligation to use Commercially Reasonable Efforts under Section 4.4 or Section 6.1.2, or if Bayer believes Atara is in breach of its cooperation obligations under Section 4.4 or Section 6.1.2, it shall so notify Bayer in writing, specifying on what grounds it believes so, and the Parties shall enter into good faith discussions about the situation. If the Parties cannot reach an agreement in this regard, then the matter shall, upon notification of either Party, be referred to the Parties' respective Executive Sponsors in accordance with the process as described in Section 20.1 for dispute resolution, provided, however, that if the Executive Sponsors cannot resolve the matter, then Atara (with respect to an alleged breach of Section 4.4 or Section 6.1.2) or Bayer (with respect to an alleged breach of Section 4.4 or Section 6.1.2) may notify the other Party of an alleged breach of contract, which notice will start the cure period pursuant to Section 18.2.2. For clarity, the effects of any violation of diligence obligations pursuant to this Agreement will in any event be limited to a right to terminate this Agreement with any other rights (such as damages, specific performance, etc.) being excluded.***

1.237 ***Disputes Related to Patent Rights. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the validity and enforceability of any Patent Rights ("Patent Matters") shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent laws of the applicable country, with a jury trial being however excluded. If such dispute involves both Patent Matters and other matters, the arbitrators will have the right to stay the arbitration until determination of Patent Matters material to the resolution of the dispute as to the other matters is resolved.***

1.238 ***Injunctive Relief. Nothing contained in this Agreement shall deny either Party the right to seek injunctive relief, equitable relief, interim or provisional relief including a temporary restraining order, specific performance, preliminary or permanent injunction or other interim equitable relief from a court of competent jurisdiction in the context of a breach or threatened breach of any provision of this Agreement, bona fide emergency or prospective irreparable harm, or as reasonable and necessary to protect its legitimate interests. Such an action may be filed and maintained, notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding concerning a dispute, if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.***

1.239 ***Interpretation.***

(a) The headings of sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.

(b) All references in this Agreement to the singular shall include the plural where applicable.

(c) The use of any gender is applicable to all genders.

(d) Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such section, and references in this Agreement to any subsection shall include all paragraphs in such subsection.

(e) Any list or examples following the word "including" shall be interpreted without prejudice to the generality of the preceding words.

(f) All references to days or years in this Agreement shall mean calendar days or years, as the case may be, unless otherwise specified.

(g) This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

1.240 ***Applicable Law. This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the Laws of New York without giving effect to any choice or conflict of law provisions.***

1.241 ***Venue. Each of the Parties hereto agrees to venue in, and submits to the exclusive jurisdiction of, the New York courts for any legal proceeding of every nature, kind and description whatsoever arising pursuant to Section 20.4 or 20.5. Both Parties agree to waive their right to a jury trial.***

1.242 ***Notices. Any notice required or permitted to be given under this Agreement by one Party to the other shall be in writing and delivered via an internationally recognized courier service with acknowledgement of receipt, and addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective upon receipt by the addressee.***

If to Bayer:	[[***]]
With a copy to (which shall not constitute notice):	[[***]]

If to Atara: [[***]]

With a copy to (which shall not constitute notice): [[***]]

1.243 ***Assignment.***

(a) Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder without the express prior written consent of the other Party; provided that: (a) either Party shall be permitted to effect such an assignment or other transfer of this Agreement, or any right or obligation hereunder, to any of its Affiliates, without the prior written consent of the non-assigning Party, provided that the assigning Party will remain liable and responsible for all of its obligations under this Agreement; and (b) either Party shall be permitted to effect such an assignment or other transfer of this Agreement, or any right or obligation hereunder without the prior written consent of the other Party, to a successor to substantially all of the business to which this Agreement pertains, whether in a merger, sale of stock, sale of assets or other transaction, provided that the assignee will expressly agree to be bound by such Party's obligations under this Agreement. Additionally, either Party shall be permitted, without the prior consent of the other Party, to assign any or all of its rights to receive payments under this Agreement to any Affiliate or Third Party.

(b) Any purported assignment or other transfer in violation of this section shall be null and void.

(c) Subject to the foregoing provisions of this section, this Agreement shall be binding upon, and shall inure to the benefit of, all permitted assigns.

1.244 ***Severability. If any provision of this Agreement shall be found to be invalid or otherwise unenforceable in whole or in part, the validity or enforceability of the remainder of this Agreement shall not be affected. Furthermore, the Parties agree that the invalid portion of an unenforceable provision or part thereof shall be superseded by an adequate provision that, to the legally permitted extent, comes closest to what the Parties would have desired at the time of conclusion of this Agreement had they considered the issue concerned.***

1.245 ***Affiliates. Each Party may perform, at such Party's exclusive option, its obligations hereunder itself or through one or more Affiliates for the avoidance of doubt and unless expressly stated otherwise in this Agreement for any particular obligation, Bayer may perform its obligations, and exercise its rights, under this Agreement itself or through any other Bayer Party or Third Party contractor. Neither Party shall permit any of its Affiliates or permitted Third Party contractors to commit any act (including any act of omission) which such Party is prohibited hereunder from committing directly. The Party so acting through its Affiliate(s) shall remain liable for the due fulfillment of its obligations by, and for any breach, act or omission of, such Affiliate(s).***

1.246 ***Independent Contractors. Nothing in this Agreement shall create, or be deemed to create, a partnership, joint venture or the relationship of principal and agent or employer and***

employee between the Parties. Neither Party shall enter into or have authority to enter into any engagement or make any representation or warranty on behalf of the other Party or otherwise bind or oblige the other Party hereto. Each Party agrees to perform under this Agreement solely as independent contractor.

1.247 ***Third Party Beneficiary. MSK is an intended third party beneficiary of the terms set forth in Sections 10.1, 11.7.4, 13.7, 16.1 and 17.1-17.3 of this Agreement to the extent related to the Licensed Technology that is in-licensed by Atara under the MSK Upstream Licenses, and NIH is an intended third party beneficiary of the terms set forth in in Sections 4.4, 6.1.2 and 16.1 of this Agreement and Exhibit 2.1.3(b) No. 1 to the extent related to the Licensed Technology that is in-licensed by Atara under the NIH Upstream License.***

1.248 ***Waiver. Any term or condition of this Agreement may be waived only by a written instrument executed by the Party waiving the benefit of a right hereunder. The waiver by a Party of any right hereunder shall not be deemed a continuing waiver of such right or of another right hereunder, whether of a similar nature or otherwise.***

1.249 ***Amendments. This Agreement (including the attached exhibit(s)) shall not be amended or otherwise modified without a written document signed by the duly authorized representative(s) of each Party.***

1.250 ***Entire Agreement. This Agreement (including the attached exhibit(s)) contains the entire understanding of the Parties with respect to the subject matter hereof. All other express or implied representations, agreements and understandings with respect to the subject matter hereof, either oral or written, heretofore made are expressly superseded by this Agreement.***

1.251 ***Priorities. In the event of any ambiguity, doubt or conflict emerging herein, the terms and conditions of this Agreement shall take precedence over the terms and conditions of any exhibit, unless the latter makes an explicit reference to the provision of this Agreement that shall be amended.***

1.252 ***Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.***

1.253 ***Counterparts; Electronic Delivery. This Agreement may be executed in counterparts, each and every one of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail. Facsimile or PDF signatures of authorized signatories of the Parties shall be deemed to be original signatures, shall be valid and binding upon the Parties, and, upon delivery, shall constitute due execution of this Agreement, provided that such electronic signing and delivery is confirmed in a written paper copy signed by and delivered to each Party promptly following electronic signing and delivery.***

[Remainder of this page intentionally left blank.]

Exhibits

Exhibit 1.8	ATA2271 Plan
Exhibit 1.38	CMC Plan
Exhibit 1.59	Existing Agreements
Exhibit 1.72	ATA3271 IND Data Package
Exhibit 1.84	Licensed Know How
Exhibit 1.85	Licensed Patent Rights
Exhibit 1.97	MOFFITT Upstream Licenses
Exhibit 1.102	MSK Upstream Licenses
Exhibit 1.130	Research Plan
Exhibit 2.1.3	Terms of Upstream Licenses
Exhibit 3.3.6	Bayer Supplier Code of Conduct
Exhibit 4.4(A)	NIH Upstream Agreement Commercial Development Plan
Exhibit 4.4(B)	NIH Benchmarks
Exhibit 7.3	Key Terms of the Manufacturing and Supply Agreement
Exhibit 9.1	Upfront License Payment
Exhibit 11.6.1	Countries for Patent Prosecution
Exhibit 12.2.2.1	Technical and Organizational IT Security Measures
Exhibit 14.2.3.2(B)	Licensed Technology Not Solely Owned by Atara

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Berlin, Germany
BAYER AG

/s/ Wolfram Carius
Wolfram Carius
EVP, Head of Cell and Gene Therapy

/s/ Marianne de Backer
Marianne de Backer
EVP, Head of Business Development & Licensing, Pharma

San Francisco, California, U.S.A.
ATARA BIOTHERAPEUTICS, INC

/s/ Pascal Touchon
Pascal Touchon
President and Chief Executive Officer

Exhibit 21.1

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of the Company as of December 31, 2020:

Subsidiary Legal Name	State or other Jurisdiction of Incorporation or Organization
Atara Biotherapeutics Australia Pty. Ltd.	Australia
Atara Biotherapeutics Ireland Limited	Ireland
Atara Biotherapeutics Netherlands B.V.	Netherlands
Atara Biotherapeutics Switzerland GmbH	Switzerland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statements No. 333-199508, No. 333-204076, No. 333-209961, No. 333-214431, No. 333-219763, No. 333-223254, No. 333-229861, No. 333-236704, and No. 333-249976 on Form S-8 of our reports dated March 1, 2021, relating to the consolidated financial statements of Atara Biotherapeutics, Inc. and subsidiaries (the "Company") and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Atara Biotherapeutics, Inc. for the year ended December 31, 2020.

/s/ *DELOITTE & TOUCHE LLP*

San Jose, California
March 1, 2021

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Pascal Touchon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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 1, 2021

/s/ Pascal Touchon
Pascal Touchon
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Utpal Koppikar, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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 1, 2021

/s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in connection with the Annual Report of Atara Biotherapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), Pascal Touchon, Chief Executive Officer of the Company, and Utpal Koppikar, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 1, 2021

/s/ Pascal Touchon
Pascal Touchon
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Utpal Koppikar
Utpal Koppikar
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Annual Report on 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.