

**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, 2019

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**

(State or other jurisdiction of incorporation or organization)

**611 Gateway Blvd., Suite 900**

**South San Francisco, CA**

(Address of principal executive offices)

**46-0920988**

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

**94080**

(Zip Code)

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Small reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

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 28, 2019 as reported by The Nasdaq Stock Market, was \$760,739,420. This calculation excludes 9,054,604 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, 2020 was 58,571,550.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive proxy statement relating to its 2020 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

	<u>Page</u>
<b><u>PART I</u></b>	
Item 1.	<a href="#"><u>Business</u></a> 4
Item 1A.	<a href="#"><u>Risk Factors</u></a> 23
Item 1B.	<a href="#"><u>Unresolved Staff Comments</u></a> 55
Item 2.	<a href="#"><u>Properties</u></a> 55
Item 3.	<a href="#"><u>Legal Proceedings</u></a> 55
Item 4.	<a href="#"><u>Mine Safety Disclosures</u></a> 55
<b><u>PART II</u></b>	
Item 5.	<a href="#"><u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u></a> 56
Item 6.	<a href="#"><u>Selected Financial Data</u></a> 58
Item 7.	<a href="#"><u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a> 59
Item 7A.	<a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a> 70
Item 8.	<a href="#"><u>Financial Statements and Supplementary Data</u></a> 71
Item 9.	<a href="#"><u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u></a> 98
Item 9A.	<a href="#"><u>Controls and Procedures</u></a> 98
Item 9B.	<a href="#"><u>Other Information</u></a> 100
<b><u>PART III</u></b>	
Item 10.	<a href="#"><u>Directors, Executive Officers and Corporate Governance</u></a> 102
Item 11.	<a href="#"><u>Executive Compensation</u></a> 102
Item 12.	<a href="#"><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></a> 102
Item 13.	<a href="#"><u>Certain Relationships and Related Transactions, and Director Independence</u></a> 102
Item 14.	<a href="#"><u>Principal Accounting Fees and Services</u></a> 102
<b><u>PART IV</u></b>	
Item 15.	<a href="#"><u>Exhibits, Financial Statement Schedules</u></a> 103
Item 16.	<a href="#"><u>Form 10-K Summary</u></a> 106

## 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. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our expectations regarding the timing of initiating clinical studies, enrolling clinical studies and reporting results of clinical studies for our programs;
- the likelihood and timing of regulatory submissions or related approvals for our product candidates;
- the potential market opportunities for commercializing our product candidates;
- 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 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 our 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;
- 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 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.*

## PART I

### Item 1. Business

#### Overview

Atara Biotherapeutics is a leading off-the-shelf, allogeneic T-cell immunotherapy company that is developing novel treatments for patients with cancer, autoimmune and viral diseases. We have several T-cell immunotherapies in clinical development and are progressing a next-generation allogeneic chimeric antigen receptor T-cell, or CAR T program. Our strategic priorities are:

- **Tab-cel®**: Atara's most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), currently in Phase 3 development for patients with Epstein-Barr virus, or EBV, associated post-transplant lymphoproliferative disease, or EBV+ PTLD, who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-associated hematologic malignancies and solid tumors;
- **ATA188**: T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis;
- **ATA2271/ATA3271**: CAR T immunotherapy targeting mesothelin, with autologous (ATA2271) to allogeneic (ATA3271) development planned; and
- **ATA3219**: Allogeneic CAR T targeting CD19 as proof-of-concept for our next generation technologies and EBV T-cell 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 that has been manufactured in advance 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, modified outside the body and then delivered back to the patient. For tab-cel®, we utilize a proprietary cell selection algorithm to select the appropriate set of cells for use based on a patient's unique immune profile. This matching process is designed to allow our cells to be administered without the pre-treatment that is required for some therapies and to reduce monitoring following administration. In addition, our manufacturing facility is capable of producing multiple types of therapies and Atara MatchMe™, our proprietary T-cell order management platform, is being developed to provide patient care teams with access to therapy.

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

We recognize that our clinical studies may not be available to all patients and we have established expanded access and compassionate use programs in instances where there is a significant patient need.

## Pipeline

Our pipeline is summarized below:

Program	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3	Registration
<b>Tab-cel<sup>®</sup></b> (tabelecleucel)	RR EBV+ PTLD following HCT	EBV		ALLELE Study			
	RR EBV+ PTLD following SOT	EBV		ALLELE Study			
	Nasopharyngeal carcinoma <sup>(1)</sup>	EBV					
	EBV+ cancers <sup>(2)</sup>	EBV					
<b>ATA188</b>	Progressive MS	EBV <sup>(3)</sup>					
<b>ATA2271</b>	Autologous CAR T Solid tumors <sup>(4,5)</sup>	Mesothelin					
<b>ATA3271</b>	Off-the-shelf, allogeneic CAR T Solid tumors <sup>(4)</sup>	Mesothelin					
<b>ATA3219</b>	Off-the-shelf, allogeneic CAR T B-cell malignancies	CD19					
<b>Other CAR T</b>	AML, B-cell malignancies, solid tumors & inf diseases	Various					

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

EBV+ PTLD: EBV-Associated 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), ATA230 (CMV), ATA368 (HPV), ATA520 (WT1) and ATA621 (BK/JCV)

- (1) Phase 1b/2 study in combination with anti-PD-1 therapy, KEYTRUDA<sup>®</sup> (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated NPC.
- (2) Phase 2 multi-cohort study planned with possible indications including EBV+ PTLD with CNS involvement, EBV+ PID/AID LPD, EBV+ LMS and other potential EBV-associated diseases
- (3) Targeted antigen recognition technology
- (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) MSK investigator-sponsored Phase 1 study (NCT02414269) of a mesothelin-targeted CAR T immunotherapy is ongoing; 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

### **Tab-cel<sup>®</sup>**

#### *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, or HCT, or solid organ transplants, or 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. Approximately 10-15% of PTLD patients are children.

Historical studies suggest a high unmet medical need for improved therapies in patients with EBV+ PTLD who 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 between 16 and 56 days, with a one-year survival rate of approximately 23% based on our evaluation of available historical outcomes data. Estimated one- and two-year survival following incomplete response to rituximab in patients with high-risk EBV+ PTLD after SOT is 36% and 0%, respectively. The use of chemotherapy in patients with EBV+ PTLD who 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 2018.

#### *Tab-cel®*

In June 2015, we licensed certain patent rights, know-how and a library of T cells and cell lines specific to EBV from MSK in an agreement we refer to as the 2015 MSK License Agreement. In the 2015 MSK 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 in development for the treatment of EBV-associated hematologic malignancies and solid tumors.

Tab-cel® is currently in Phase 3 development for the treatment of patients with EBV+ PTLD who have failed rituximab or rituximab plus 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 2018. Tab-cel® received Breakthrough Therapy Designation, or BT, from the U.S. Food and Drug Administration, or FDA, for the treatment of patients with EBV+ PTLD after HCT who have failed rituximab, Priority Medicines, or PRIME, designation from the European Medicines Agency, or EMA, for the same indication, and orphan designation in the U.S. and European Union for the treatment of patients with EBV+ PTLD following HCT or SOT.

Tab-cel® is also under development for other EBV-associated hematologic malignancies and solid tumors through a multi-cohort study, and for nasopharyngeal carcinoma, or NPC, in a separate clinical study.

#### *Tab-cel® for EBV+ PTLD*

In clinical studies conducted at MSK that have enrolled patients with EBV+ 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 one-year overall survival of approximately 70% in two separate clinical studies. In the setting of EBV+ PTLD after SOT in patients who have failed rituximab, similar results were observed, with one-year overall survival of approximately 60% 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 3 studies for tab-cel® intended to support approval in two separate indications, the treatment of EBV+ 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).

The Phase 3 MATCH study was a multicenter, open label, single arm study designed to enroll approximately 35 patients with EBV+ PTLD following HCT who have failed rituximab. The Phase 3 ALLELE study was initially a multicenter, open label study designed with two non-comparative cohorts of approximately 35 patients each. The first cohort included patients who previously received rituximab monotherapy, and the second cohort included patients who previously received rituximab plus chemotherapy. The primary endpoint of both the MATCH and ALLELE studies was confirmed best objective response rate, or ORR, defined as the percent of patients achieving either a complete or partial response to treatment with tab-cel® confirmed after the initial tumor assessment showing a response.

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 an SOT cohort for EBV+ PTLD patients who have failed rituximab with both chemotherapy and non-chemotherapy prior treatment experience. The primary endpoint of ALLELE remains as confirmed best ORR, as determined by independent review, and 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. Secondary endpoints include duration of response, overall survival, safety, quality of life metrics, and other measures to evaluate its health economic impact. Additionally, we expect to expand the ALLELE study geographically to include clinical sites outside the U.S. We submitted clinical trial applications, or CTAs, to several European countries in 2019 to enable opening EU clinical sites in 2020, and our CTAs in Austria, Spain and the United Kingdom have been approved.

We plan to initiate a biologics license application, or BLA, submission for patients with EBV+ PTLD to the FDA in the second half of 2020. We plan to discuss the totality of tab-cel® results with the FDA in a pre-BLA meeting prior to initiating the BLA submission.

We are also planning the submission of a marketing authorization of tab-cel® in the European Union. In February 2016, tab-cel® was granted orphan drug designation by the European Commission for the treatment of patients with post-transplant lymphoproliferative disorder. Tab-cel® has also been granted access to the PRIME scheme. PRIME is a program launched by the EMA to enhance support for the development of medicines that target an unmet medical need. This voluntary program is based on enhanced interaction and early dialogue with developers of promising medicines, to optimize development plans and speed up evaluation so these medicines can reach patients earlier. The program focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by EMA. To be accepted for PRIME, a medicine must show its potential to benefit patients with unmet medical needs based on early clinical data. We remain in discussions with the European Medicines Agency, or EMA. We have submitted a Pediatric Investigation Plan, or PIP, to EMA. Following an agreement with EMA on the PIP, we plan to submit a tab-cel® EU marketing authorization application for patients with EBV+ PTLD in 2021.

We are continuing our preparations to support the planned commercialization of tab-cel®. This includes the development of our proprietary T-cell order management platform, Atara MatchMe™, that is being developed to provide patient care teams with access to therapy through a web-based interface. We expect to pursue approvals in key geographies and may seek partners to aid in our commercialization efforts in select markets.

#### *Tab-cel® Multi-Cohort Study*

We expect to pursue development of tab-cel® in earlier lines of therapy, including in our planned Phase 2 multi-cohort study. We expect to initiate enrollment in this study including up to six additional EBV+ ultra-rare diseases for patients, in the second half of 2020 based on previous clinical experience treating these patients.

#### *Tab-cel® for NPC*

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-associated NPC. This Phase 1b/2 study, which was initiated in the fourth quarter of 2018, will evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the combination. We enrolled the final planned patient in the Phase 1b part of the study in February 2020. Based on our market research, we estimate the incidence during 2018 of NPC in the U.S., United Kingdom, France, Italy and Spain was collectively approximately 3,800 patients and approximately 71,000 patients in East Asia. Our study is designed to address a sub-population of the total incidence of this disease.

#### *EAP and SPU Programs*

Atara continues to see strong tab-cel® investigator, physician and patient interest and, for cases in which we are not able to enroll patients in its EBV+ PTLD Phase 3 clinical study, we are providing tab-cel® to patients in need under our expanded access protocol, or EAP, and single patient use, or SPU, programs. The primary objective of these programs is to provide tab-cel® monotherapy to patients with EBV-associated diseases or certain EBV+ malignancies for whom there are no other therapeutic options.

#### **ATA188**

##### *Multiple Sclerosis*

Atara is also developing ATA188, a T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis, or MS. MS is a chronic autoimmune disorder of the central nervous system, or 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 more-than two million people worldwide affected by MS, with approximately 800,000 diagnosed prevalent cases of MS in the U.S. and EU in 2019.

There are two categories of MS: progressive MS, or PMS, and relapsing-remitting MS, or 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, or PPMS, and secondary progressive MS, or SPMS. Published reports indicate that together, PPMS and SPMS make up approximately 43% of MS patients. 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.

### *ATA188*

We licensed rights to certain know-how and technology from QIMR Berghofer that uses targeted antigen 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, or 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 Phase 1 dose escalation cohort was completed in the third quarter of 2019 and we presented initial efficacy and updated safety results from this study in September 2019 at the 35<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). These results were based on data as of July 29, 2019, and showed that across four planned dose cohorts, ATA188 was well tolerated in PMS patients, with no evidence of cytokine release syndrome, graft versus host disease or dose-limiting toxicities.









Following a six-month assessment of patients in cohort 3 of this study, we selected this cohort 3 dose to initiate the randomized, double-blind, placebo-controlled Phase 1b part of this study, for which we plan to initiate enrollment for patients with PMS in the second or third quarter of 2020. We expect to present six- and twelve-month ATA188 Phase 1a clinical results for cohorts 3 and 4 in the first and second halves of 2020, respectively.

In addition to ATA188, QIMR Berghofer had previously completed a Phase 1 study of ATA190, an autologous EBV-specific T-cell preparation that utilizes the same approach to targeted antigen recognition as ATA188, for the treatment of patients with PMS. Based on continued encouraging ATA188 results, acceleration of the ATA188 randomized Phase 1b study and the Company's strategic focus on off-the-shelf, allogeneic T-cell immunotherapies, Atara does not plan to initiate a randomized study of ATA190 in PMS at this time and will evaluate strategic options for this program.

### CAR T Programs

Our current CAR T pipeline is as follows:

	Indication	Target	CAR T Technologies	
ATA2271	Autologous Solid tumors <sup>(1)</sup>	Mesothelin	PD-1 DNR 1XX co-stimulation	 Memorial Sloan Kettering Cancer Center
ATA3271	Off-the-shelf, allogeneic Solid tumors <sup>(1)</sup>	Mesothelin	PD-1 DNR 1XX co-stimulation	 ATARA BIO <sup>®</sup>
ATA3219	Off-the-shelf, allogeneic B-cell malignancies	CD19	1XX co-stimulation	 ATARA BIO <sup>®</sup>
ATA2321	Autologous AML	Dual-targeted undisclosed	Novel co-stimulation	 MOFFITT CANCER CENTER
ATA2431	Autologous B-cell malignancies	CD19-CD20- CD22	Novel co-stimulation	 MOFFITT CANCER CENTER
Other CAR T	Solid tumors & infectious diseases	Undisclosed	1XX co-stimulation	 Memorial Sloan Kettering Cancer Center

AML: acute myeloid leukemia; DNR: Dominant Negative Receptor

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

#### ATA2271/ATA3271

Atara's pipeline includes next-generation CAR T immunotherapies for patients with hematologic malignancies and solid tumors, and viral diseases, including ATA2271 and ATA3271 targeting mesothelin, which are partnered with MSK. 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.

We have prioritized our mesothelin-targeted next-generation CAR T program, which consists of ATA2271 and ATA3271. Results presented by our collaborators at MSK have demonstrated that their regionally-delivered mesothelin-targeted, 1<sup>st</sup> generation autologous CAR T cells were well tolerated and showed encouraging anti-tumor activity in combination with pembrolizumab, a PD-1 checkpoint inhibitor. These collaborator results support our planned development of ATA2271, a next-generation, mesothelin-targeted autologous CAR T immunotherapy using MSK's novel 1XX CAR signaling domain and PD-1 dominant negative receptor, or DNR, checkpoint inhibition technologies for patients with mesothelin-associated solid tumors. We expect our collaborators at MSK to submit an investigational new drug, or IND, application to the FDA for ATA2271 for patients with advanced mesothelioma in the second or third quarter of 2020. In parallel, we are conducting preclinical work on an allogeneic version of this mesothelin CAR T program, ATA3271.

## ATA3219

We are also developing ATA3219, an off-the-shelf allogeneic CAR T immunotherapy targeting CD19 for patients with B-cell lymphomas, to serve as a potential proof-of-concept for our next generation technologies and allogeneic EBV CAR T platform.

In February 2020, an academic off-the-shelf, allogeneic CD19 CAR T clinical study using an EBV T-cell construct for patients with relapsed/refractory B-cell malignancies was presented at the 2020 Transplantation and Cellular Therapy (TCT) Meetings. Findings from this study provide 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 and durable responses, low risk of toxicity and that can be rapidly delivered to patients.

### ***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, or 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 novel CAR T intracellular co-stimulatory domains that may improve CAR T proliferation when responding to an appropriate antigen and enhance CAR T persistence by reducing T-cell exhaustion.

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 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 drug candidates currently in development for the same indications.

### ***EBV+ PTL D***

There are currently no FDA- or EMA-approved products for the treatment of EBV+ PTL D. However, some marketed products and therapies are used off-label in the treatment of EBV+ PTL D, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing drug candidates for EBV+ PTL D and other EBV-associated diseases including: ViraActa 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 including EBV and is planning to initiate several Phase 3 studies in the next year and Tessa Therapeutics Pte Ltd., or Tessa, which has a preclinical product candidate that is an allogeneic CD30-targeted CAR EBV-specific T-cell therapy.

## **NPC**

Drug therapies approved or commonly used for the treatment of NPC include radiation therapy, often given in combination with chemotherapy, and cetuximab, a monoclonal antibody targeting epidermal growth factor receptor, or EGFR. Surgery for NPC is also occasionally used after chemoradiotherapy or to treat relapsed/refractory NPC. Several development candidates are being evaluated for NPC. Tessa is evaluating TT10, an autologous, EBV-specific T-cell product, in a phase 3 clinical study for advanced NPC. In addition, a number of companies are evaluating immunotherapies in combination with PD1/PDL1 inhibitors for the treatment of head and neck cancers, including NPC. These include Bristol-Myers Squibb Company's ipilimumab, relatlimab and daratumumab, Roche Pharmaceuticals' bevacizumab and AstraZeneca PLC's tremelimumab.

## **Multiple Sclerosis**

Competition in the MS market is high with at least seventeen therapies, including three generics, approved for the treatment of RRMS in the U.S. and EU. There are many competitors in the RRMS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Vumerity™ (diroximel fumarate), marketed by Biogen, and Mayzent® (siponimod), marketed by Novartis, were approved for the treatment of relapsing forms of MS in the U.S (Vumerity) and EU (Mayzent). There are numerous development candidates in Phase 3 studies for RRMS including TG Therapeutics' anti-CD20 monoclonal antibody ublituximab and EMD Serono's BTK inhibitor, evobrutinib. Novartis' anti-CD20 monoclonal antibody ofatumumab and J&J/Janssen's sphingosine-1-phosphate receptor 1 (S1P1) modulator, ponesimod have completed their Phase 3 studies and have filed (ofatumumab) or plan to file (ponesimod) for regulatory approval in the future. Celgene's ozanimod, an S1PR1 and S1PR5 agonist is awaiting FDA and EMA regulatory approval with a Prescription Drug User Fee Act, or PDUFA, date in March 2020, and EMA in the first half of 2020.

Six therapies have been approved for the treatment of PMS. Ocrevus® is approved in the U.S. and EU for the treatment of PPMS. Extavia® (marketed by Novartis) and Betaferon® (marketed by Bayer AG) are approved in the European Union for the treatment of SPMS when disease is active, or active SPMS. Mayzent® (siponimod), marketed by Novartis and Mavenclad® (cladribine), marketed by EMD Serono, were most recently approved for the treatment of active SPMS in the U.S. and EU (Mayzent). In addition, mitoxantrone, which is now generic, is approved to treat SPMS in the U.S.

The SPMS and PPMS markets have active development pipelines and additional novel agents could be approved in the future. Several development candidates are being evaluated in Phase 3 studies for progressive forms of MS including primary and secondary progressive MS. These are MedDay's MD-1003, a concentrated form of biotin, and AB Science's masitinib, a tyrosine kinase inhibitor. Medicinova is planning to initiate a Phase 3 study of its PDE inhibitor, ibudilast (MN166) in patients with non-relapsing secondary progressive MS.

## **CAR T Program**

There are currently two CAR T therapies approved in the U.S. and EU, Novartis' Kymriah (tisagenlecleucel) and Gilead/Kite's Yescarta (axicabtagene ciloleucel). Bristol-Myers Squibb filed its BLA with the FDA for lisocabtagene maraleucel (liso-cel) in December 2019. There are more than 100 CAR T's in development including at least 35 which are allogeneic and off-the-shelf cell therapies. Depending on the diseases that our CAR T therapies target in the future, we may face competition from both CAR T therapies and other modalities, such as small molecules and antibodies, in the indication of interest.

## **Terms of Certain License and Research and Development Collaboration Agreements**

### **2015 MSK License Agreement**

In June 2015, we entered into the 2015 MSK License Agreement. Under the terms of the 2015 MSK License Agreement, 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 T-cell products specific to cytomegalovirus, or CMV, EBV or WT1 that comprise or are based on or made using these licensed rights. We agreed to use commercially reasonable efforts to commercialize the licensed products and, if commercialized, continue active marketing efforts for any commercialized licensed product through the term of the license agreement.

Under the 2015 MSK License Agreement, we are obligated to make milestone payments of up to \$33.0 million with respect to the three licensed clinical stage T-cell programs based on achievement of specified development, regulatory and sales-related milestones. We are also required to make escalating mid to high single-digit royalty payments to MSK based on sales of any licensed products. 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 consideration we receive for sublicensing the licensed rights.

The 2015 MSK License Agreement expires for each licensed T-cell product on a licensed product-by-licensed product basis and a country-by-country basis, on the latest of: (i) expiration of the last licensed patent rights related to a licensed product in a country, (ii) expiration of any market exclusivity period granted by law with respect to a licensed product in a country, and (iii) a specified number of years after the first commercial sale of the licensed product in a country. Upon expiration of the 2015 MSK License Agreement, the licenses granted to us will become non-exclusive royalty-free, perpetual and irrevocable. MSK may terminate the 2015 MSK License Agreement if we materially breach the agreement and do not cure this breach within a specified period or if we experience certain insolvency events.

In May and December 2018, we licensed additional CAR T-related 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 Agreement and Research and Development Collaboration Agreement***

In September 2016, we entered into an amended and restated license agreement and an amended and restated research and development collaboration agreement with QIMR Berghofer, each of which amended and restated prior agreements entered into with QIMR Berghofer in October 2015. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019 to eliminate our license to certain rights related to CMV. We refer to our August 2019 second amended and restated license agreement with QIMR Berghofer as the QIMR License Agreement and our August 2019 second amended and restated research and development collaboration agreement with QIMR Berghofer as our QIMR Collaboration Agreement.

Under the QIMR License Agreement and QIMR Collaboration Agreement, we possess an exclusive, worldwide license to develop and commercialize allogeneic T-cell programs utilizing technology and know-how developed by QIMR Berghofer.

The QIMR License Agreement provides for various milestone payments of up to \$15 million 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 of up to \$7 million to QIMR Berghofer based on 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, or 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 43 patent families having a total of more than 245 issued patents or patent applications. Our patents and patent applications (if issued) are expected to expire between 2022 and 2040, 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 seven different trademark families comprised of more than 100 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, or 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, or FDCA, the Public Health Service Act, or 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, or 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, or 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, or 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, or GTPs, for the use of human cellular and tissue products;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure 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 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 the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals 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 that 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 PDUFA, as amended, 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 will determine whether a Risk Evaluation and Mitigation Strategy, or 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. These 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, or 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, or 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, or 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. 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 U.S. presidential administration laid out a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains 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. The Department of Health and Human Services, or HHS, has started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. In January 2019, the HHS Office of Inspector General proposed modifications to U.S. federal healthcare Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although some of these and other proposals may require authorization through additional legislation to become effective, members of Congress and the presidential administration have indicated that they will continue to seek new legislative or administrative measures to control drug costs. 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.

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, or 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, or 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 and the Health Care and Education Reconciliation Act, or 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, the President signed Executive Orders designed to delay 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.

### ***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 clinical study application, or CTA, which is much like an IND in the U.S., prior to the commencement of human clinical studies. In Europe, for example, 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.

Under EU regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. 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 European Medicines Agency, or 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 PRiority MEdicines, or 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 Pediatric Investigation Plan, or 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.

### ***Additional Regulation***

As a pharmaceutical 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. Commercial production qualification activities for our facility are progressing well and, together with our contracted manufacturing partner, are aligned with our planned commercial product supply strategy.

In December 2019, we entered into a Commercial Manufacturing Services Agreement, or the Manufacturing Agreement, with Cognate Bioservices, Inc., or Cognate. The Manufacturing Agreement supersedes the Development and Manufacturing Services Agreement, or the DMSA Agreement, with Cognate dated August 10, 2015, as amended. The Manufacturing Agreement governs similar manufacturing services provided for under the DMSA Agreement with similar terms. Specifically, 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. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of services for at least ninety days. In connection with the entry into the Manufacturing Agreement, we and Cognate also entered into a Fifth Amendment to the DMSA Agreement, which amended the expiration date of the DMSA Agreement to December 31, 2019.

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, or 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, or GMPs, as well as Good Tissue Practices, or GTPs. 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, tissues and cellular- and tissue-based products, or 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.

## **Employees**

As of December 31, 2019, we had 393 employees. We consider our relations with our employees to be good.

## **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](http://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, or 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](http://www.sec.gov).

## Item 1A. Risk Factors

*Investing in our common stock 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 common stock.*

*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 common stock 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 a product candidate 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 or otherwise to date, 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, 2019, we reported a net loss of \$291.0 million and we had an accumulated deficit of \$818.0 million as of December 31, 2019.

We do not expect to generate revenues for the foreseeable 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. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We 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 source of revenues. We may never generate revenues or achieve profitability.***

To date, we have not generated any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when we will generate revenues 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 and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical studies;
- 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 or treatment guidelines, 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 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, 2019, together with net proceeds from the sale of our common stock from our 2019 ATM Facility in January 2020, described in Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources section of this Annual Report on Form 10-K, will be sufficient to fund our planned operations into the second quarter of 2021. As of December 31, 2019, we had total cash, cash equivalents and short-term investments of \$259.1 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. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We do not have any committed external source of funds. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. 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 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. 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 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 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 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, which we do not expect will occur for several years, if ever, 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 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® 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 that which 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.

In January 2019, the U.S. federal government entered a prolonged shutdown suspending services deemed non-essential, including certain activities of the FDA, and U.S. politicians have expressed interest in future similar shutdowns as a negotiating tactic. Our development and commercialization activities could be harmed or delayed by a similar shutdown of the U.S. federal government in the future, which may significantly delay the FDA's ability to timely 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;
- 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 and 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 approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market requirements, and additional information informing benefits or risks of our products may emerge 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 will demonstrate adequate efficacy and safety to result in regulatory approval to market tab-cel<sup>®</sup>, 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, submit a filing on the basis of interim data from a subset of the required patients or submit a filing on the basis of the final data. A filing based on interim data would impact the required ORR.

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-associated malignancies, including EBV+ PTLD after HCT and EBV+ PTLD after SOT. These Phase 2 studies were not prospectively designed to evaluate the efficacy of tab-cel® in the treatment of a single disease state for which we may later seek approval. 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.

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 such as ATA188 may not yield the same or better results as compared to an autologous product candidate such as ATA190. 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 our clinical studies that we 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 may announce or share with regulatory authorities interim “top line” or preliminary data from our clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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 we 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:

- 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, or 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, or 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 suitable 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;
- 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 for the same indication that we are treating;
- 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 indications 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 ability to manufacture the requisite materials for a study;
- risk that we do not have appropriately matched HLA cell lines; and
- 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 indications we are investigating.

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<sup>®</sup> 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<sup>®</sup>, 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. 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.

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 may experience in our clinical studies, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our studies could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing 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 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 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. Further, new studies may change the estimated incidence or prevalence of these diseases. 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. 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. and Europe, 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 drug 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.



***Breakthrough Therapy Designation by the FDA 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 Breakthrough Therapy Designation, or BTB, for tab-cel® for EBV+ PTLB, 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.

Designation as a breakthrough therapy is within the discretion of the FDA. Receipt of a BTB for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited the FDA review procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the conditions for qualification and rescind BTB or decide that the time period for FDA 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 European Union, 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, 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, or 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, or cGMP, current Good Clinical Practices, or GCP, current good tissue practices, or 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 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, or the DOJ, the Office of Inspector General of the 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. 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.

***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 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 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 earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors.

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 at least a portion of our product candidates ourselves. Delays in commissioning and receiving regulatory approvals for 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 our facility are delayed, we may not be able to manufacture sufficient quantities of our drug 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 drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug 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 approved by 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 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.

To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tab-cel<sup>®</sup>, 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 standards and 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, or 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 reasonable 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 could 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. 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. Third-party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. 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 changes the way health care is financed by both governmental and private insurers, and significantly impacts 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 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, or 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.

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, the President signed Executive Orders designed to delay 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, 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. On December 18, 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.

It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. The U.S. Congress may consider and adopt other legislation to repeal and replace all or certain elements of the Affordable Care Act. Any other executive, legislative or judicial action to "repeal and replace" all or part of the Affordable Care Act may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the Affordable Care Act or the implementation of new health care legislation, could result in significant changes to the health care system which may adversely affect our business in unpredictable ways.

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 FDA 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. Additionally, in May 2018, the U.S. presidential administration laid out a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains 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. HHS has started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. In January 2019, the HHS Office of Inspector General proposed modifications to U.S. federal healthcare Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although some of these and other proposals may require additional authorization to become effective, members of Congress and the presidential administration have indicated that they will continue to seek new legislative or administrative measures to control drug costs. 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.

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 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 drug candidates for EBV+ PTLD and other EBV-associated diseases including: ViraActa 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 including EBV and is planning to initiate several Phase 3 studies in the next year and Tessa Therapeutics Pte Ltd., or Tessa, which has a preclinical product candidate that is an allogeneic CD30-targeted CAR EBV-specific T-cell therapy.

Competition in the MS market is high with at least seventeen therapies, including three generics, approved for the treatment of relapsing-remitting multiple sclerosis, or RRMS, in the U.S. and EU. There are many competitors in the RRMS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Vumerity™ (diroximel fumarate), marketed by Biogen was approved in the U.S. for the treatment of relapsing forms of MS and Mayzent® (siponimod), marketed by Novartis, was approved in the EU for the same indication. There are numerous development candidates in Phase 3 studies for RRMS including TG Therapeutics' anti-CD20 monoclonal antibody ublituximab and EMD Serono's BTK inhibitor, evobrutinib. Novartis has completed a Phase 3 study for its anti-CD20 monoclonal antibody, ofatumumab, and has sought regulatory approval for this candidate. In addition, J&J/Janssen has completed a Phase 3 study for its sphingosine-1-phosphate receptor 1 (S1P1) modulator, ponesimod, and plans to file for regulatory approval in the future. Celgene's ozanimod, an S1PR1 and S1PR5 agonist, is awaiting FDA and EMA regulatory approval with a PDUFA date in March 2020, and EMA in the first half of 2020.

Six therapies have been approved for the treatment of progressive MS. Ocrevus® is approved in the U.S. and EU for the treatment of PPMS. Extavia® (marketed by Novartis) and Betaferon® (marketed by Bayer AG) are approved in the European Union for the treatment of secondary progressive MS when disease is active, or active SPMS. Mayzent® (siponimod), marketed by Novartis and Mavenclad® (cladribine), marketed by EMD Serono, were most recently approved for the treatment of active SPMS in the U.S. and EU (Mayzent) Prior to the approvals of Mayzent and Mavenclad in 2019, there was only one drug (mitoxantrone) approved to treat SPMS in the U.S., which is now generic.

The SPMS and PPMS markets have active development pipelines and additional novel agents could be approved in the future. Several development candidates are being evaluated in Phase 3 studies for progressive forms of MS including primary and secondary progressive MS. These are MedDay's MD-1003, a concentrated form of biotin, and AB Science's masitinib, a tyrosine kinase inhibitor. Medicinova is planning to initiate a Phase 3 study of its PDE inhibitor, ibudilast (MN166) in patients with non-relapsing secondary progressive MS.

There are currently two CAR T therapies approved in the U.S. and EU, Novartis' Kymriah (tisagenlecleucel) and Gilead/Kite's Yescarta (axicabtagene ciloleucel). Bristol-Myers Squibb filed its BLA to the US FDA for lisocabtagene maraleucel (liso-cel) in December 2019. There are more than 100 CAR T therapies in development including at least 35 which are allogeneic and off-the-shelf cell therapies. Depending on the diseases that we target in the future, we may face competition from both CAR T 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, including EBV+ 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, or biologics, and therefore they may be subject to competition sooner than anticipated.***

The Biologics Price Competition and Innovation Act of 2009, or 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.***

We are at any 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 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, 2019, we had 393 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;
- 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 Our Business Generally**

***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, 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 pharmaceutical 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 will constrain 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 and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions available under the federal civil False Claims Act, 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, or 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, or 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;
- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- 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.

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 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.

***Our business and operations would suffer in the event of computer system failures or security breaches.***

Our internal computer systems, and those of our partners, our CROs, our CMOs, and other business vendors on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. 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.

***Legislation or other changes in tax law could adversely affect our business and financial condition.***

Legislation or other changes in tax laws could lead to or increase our tax liability and adversely affect our after-tax profitability. For example, The Tax Act was enacted in the U.S. on December 22, 2017. 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. The Tax Act among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We completed an evaluation of the overall impact of The Tax Act on our effective tax rate and balance sheet through December 31, 2019 and have reflected the amounts in our financial statements. The U.S. Department of Treasury has issued and will continue to issue additional regulations and interpretive guidance that may impact how we will apply the law. The Tax Act or any future legislation may have a significant impact in future periods and our business and financial condition could be adversely affected. The future impact of the Tax Act or any future legislation on holders of our common stock is also uncertain and could be adverse.

***Our ability to use net operating loss carryforwards to offset future taxable income, and our ability to use tax credit carryforwards, may be subject to certain limitations.***

Our ability to use our federal and state net operating losses, or 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, 2019, we reported U.S. federal and state NOLs of approximately \$547.7 million and \$695.4 million, respectively. Our federal NOLs generated prior to 2018 aggregating to \$77.1 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 2032. Accordingly, these federal and state NOLs could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOL's is limited to 80% of current year taxable income. Not all states conform to the Tax Act and other states have varying conformity to the Tax Act.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or 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, 2019 and concluded that we have experienced ownership changes since inception that we believe under Section 382 of the Code will result in limitations in our ability to use certain of our 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 2017 and before, 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.

***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 manmade 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.

**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, 2017 through December 31, 2019, the reported sale price of our common stock has fluctuated between \$10.38 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. 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 trading volume levels of our shares;
- 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. 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 health care 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 and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

Our executive officers, directors and 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. 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, or Certificate of Incorporation, and amended and restated bylaws, or 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.

#### **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 April 2021. 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, 2020, there were 9 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.

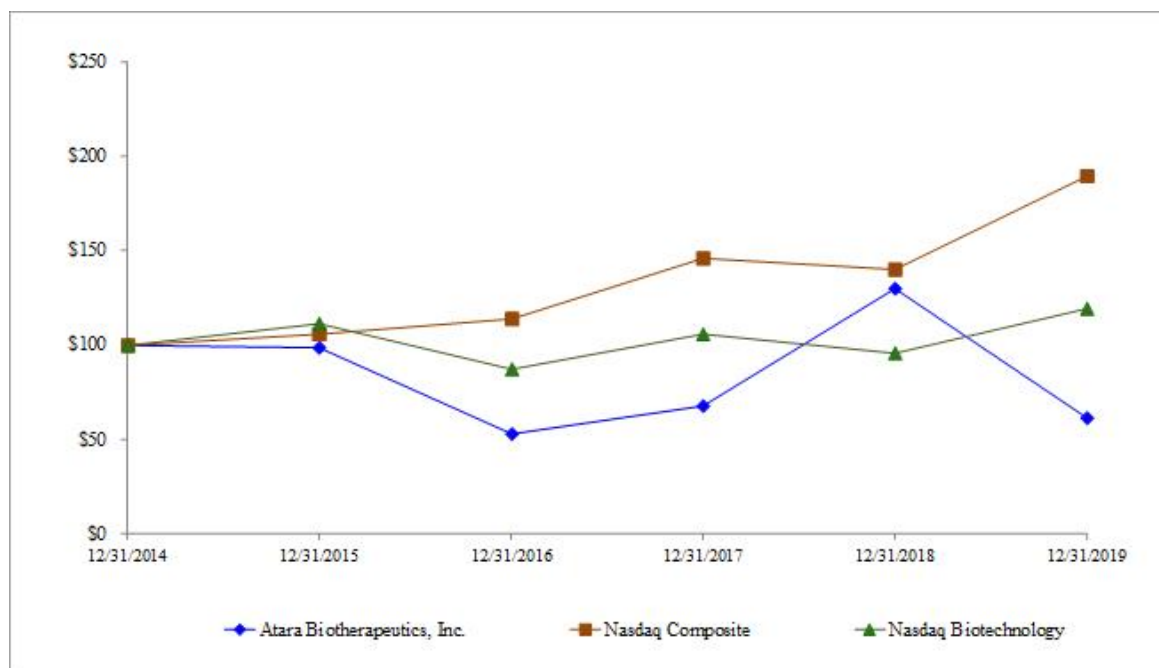


## Stock Performance Graph

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, 2019, 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
2014	\$ 100.00	\$ 100.00	\$ 100.00
2015	98.73	105.73	111.42
2016	53.08	113.66	87.26
2017	67.66	145.76	105.64
2018	129.87	140.10	95.79
2019	61.57	189.45	119.17

## Item 6. Selected Consolidated 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, 2019 and 2018 and for the years ended December 31, 2019, 2018 and 2017, 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,				
	2019	2018	2017	2016	2015
	(In thousands, except per share amounts)				
Operating expenses:					
Research and development	\$ 216,097	\$ 167,457	\$ 81,206	\$ 56,514	\$ 41,618
General and administrative	79,584	69,654	40,326	24,728	16,830
Total operating expenses	295,681	237,111	121,532	81,242	58,448
Loss from operations	(295,681)	(237,111)	(121,532)	(81,242)	(58,448)
Interest and other income, net	4,717	6,368	2,027	2,203	1,218
Loss before provision for income taxes	(290,964)	(230,743)	(119,505)	(79,039)	(57,230)
Provision for (benefit from) income taxes	12	(44)	(14)	10	(9)
Net loss	\$ (290,976)	\$ (230,699)	\$ (119,491)	\$ (79,049)	\$ (57,221)
Other comprehensive gain (loss):					
Unrealized gain (loss) on available-for-sale securities	560	(189)	32	335	(418)
Comprehensive loss	\$ (290,416)	\$ (230,888)	\$ (119,459)	\$ (78,714)	\$ (57,639)
Basic and diluted net loss per common share	\$ (5.67)	\$ (5.27)	\$ (4.00)	\$ (2.75)	\$ (2.24)

Consolidated Balance Sheet Data:	As of December 31,				
	2019	2018	2017	2016	2015
	(In thousands)				
Cash, cash equivalents and short-term investments	\$ 259,109	\$ 309,631	\$ 166,096	\$ 255,682	\$ 320,482
Working capital	\$ 236,249	\$ 281,510	\$ 144,544	\$ 250,878	\$ 314,888
Total assets	\$ 342,942	\$ 391,839	\$ 217,779	\$ 263,914	\$ 324,975
Long-term liabilities	\$ 15,418	\$ 13,003	\$ 12,269	\$ 503	\$ 166
Total stockholders' equity	\$ 290,781	\$ 338,857	\$ 177,864	\$ 253,736	\$ 315,100

## 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 leading off-the-shelf, allogeneic T-cell immunotherapy company that is developing novel treatments for patients with cancer, autoimmune and viral diseases. We have several T-cell immunotherapies in clinical development and are progressing a next-generation allogeneic chimeric antigen receptor T-cell, or CAR T program. Our strategic priorities are:

- **Tab-cel®:** Atara’s most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), currently in Phase 3 development for patients with Epstein-Barr virus, or EBV, associated post-transplant lymphoproliferative disease, or EBV+ PTLN, who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-associated hematologic malignancies and solid tumors;
- **ATA188:** T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis;
- **ATA2271/ATA3271:** CAR T immunotherapy targeting mesothelin, with autologous (ATA2271) to allogeneic (ATA3271) development planned; and
- **ATA3219:** Allogeneic CAR T targeting CD19 as proof-of-concept for our next generation technologies and EBV T-cell 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 that has been manufactured in advance 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, modified outside the body and then delivered back to the patient. For tab-cel®, we utilize a proprietary cell selection algorithm to select the appropriate set of cells for use based on a patient’s unique immune profile. This matching process is designed to allow our cells to be administered without the pre-treatment that is required for some therapies and to reduce monitoring following administration. In addition, our manufacturing facility is capable of producing multiple types of therapies and Atara MatchMe™, our proprietary T-cell order management platform, is being developed to provide patient care teams with access to therapy.

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

We recognize that our clinical studies may not be available to all patients and we have established expanded access and compassionate use programs in instances where there is a significant patient need.

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. Commercial production qualification activities for our facility are progressing well and, together with our contracted manufacturing partner, are aligned with our planned commercial product supply strategy.

In December 2019, we entered into a Commercial Manufacturing Services Agreement, or the Manufacturing Agreement, with Cognate, effective as of January 2020. The Manufacturing Agreement supersedes the DMSA Agreement with Cognate and governs similar manufacturing services provided for under the DMSA Agreement with similar terms. Specifically, 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. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of services for at least ninety days. In connection with the entry into the Manufacturing Agreement, we and Cognate also entered into a Fifth Amendment to the DMSA Agreement, which amended the expiration date of the DMSA Agreement to December 31, 2019.

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 \$291.0 million, \$230.7 million and \$119.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of \$818.0 million. 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, 2019, our cash, cash equivalents and short-term investments totaled \$259.1 million, which we intend to use to fund our operations.

## **Financial Overview**

### ***Revenues***

We have never generated revenues and have incurred losses since inception. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties.

### ***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 to develop product candidates based on our next-generation CAR T programs;
- continuing development of ATA188 in progressive MS;
- continuing to develop our product candidates in additional indications, including tab-cel® for NPC and 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;
- future clinical study results;
- uncertainties in clinical study enrollment rates or discontinuation rates of patients;
- 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; 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; outside professional service 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. We anticipate that our general and administrative expenses will continue to increase in the future to support our continued research and development and the potential commercialization of one or more of our product candidates.

#### ***Interest and Other Income, net***

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

### 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 our consolidated 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.

Description	Judgments and Uncertainties	Effect if Actual Results Differ from Assumptions
<p><b>Accrued Research and Development Expenses</b></p> <p>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.</p>	<p>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.</p>	<p>For the years ended December 31, 2019 and 2018, there were no material changes from our estimates of accrued research and development expenses.</p> <p>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.</p>

<p><b>Stock-based Compensation</b></p> <p>We have stock-based compensation programs, which include restricted stock agreements, or RSAs; restricted stock units, or RSUs; stock options' and an employee stock purchase plan. See Note 2– “Summary of Significant Accounting Policies” and Note 9 – “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 RSAs, 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 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.</p>	<p>Assumptions for the Black-Scholes valuation model used for employee stock awards include:</p> <p>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.</p> <p>Expected volatility – Expected volatility is estimated using comparable public companies' volatility for similar terms.</p> <p>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%.</p> <p>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.</p> <p>The fair value of our common stock is based on observable market prices.</p>	<p>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.</p>
<p><b>Accounting for Income Taxes</b></p> <p>See Note 10 – “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, 2019.</p>	<p>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.</p> <p>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.</p>	<p>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 \$205.2 million as of December 31, 2019 related primarily to net operating losses, capitalized expenses and stock-based compensation.</p>

## 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, 2019, 2018, and 2017.

## Results of Operations

### Comparison of the Years Ended December 31, 2019, 2018 and 2017

#### Research and development expenses

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

	Year ended December 31,			(Decrease) Increase	
	2019	2018	2017	2019 compared to 2018	2018 compared to 2017
			(in thousands)		
Tab-cel <sup>®</sup> expenses	\$ 49,179	\$ 50,822	\$ 33,653	\$ (1,643)	\$ 17,169
ATA188, CAR T and other program expenses	34,869	30,155	9,243	4,714	20,912
Employee and overhead expenses	132,049	86,480	38,310	45,569	48,170
Total research and development expenses	<u>\$ 216,097</u>	<u>\$ 167,457</u>	<u>\$ 81,206</u>	<u>\$ 48,640</u>	<u>\$ 86,251</u>

Tab-cel<sup>®</sup> expenses were \$49.2 million in 2019 as compared to \$50.8 million in 2018 and \$33.7 million in 2017. Tab-cel<sup>®</sup> expenses decreased slightly in 2019 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. The increase in 2018 was primarily due to clinical study, manufacturing and outside service costs related to the MATCH and ALLELE Phase 3 clinical studies, which were initiated in December 2017. We anticipate that tab-cel<sup>®</sup> expenses will increase in 2020 due to the addition of trial sites outside of the U.S., as well as the initiation of our Phase 2 multi-cohort study.

ATA188, CAR T and other program expenses were \$34.9 million in 2019 as compared to \$30.2 million in 2018 and \$9.2 million in 2017. 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 the ATA190 program. The increase in 2018 was primarily related to (a) one-time license fees of \$12.5 million incurred in the fourth quarter of 2018 for exclusive rights to a next-generation allogeneic CAR T program targeting mesothelin from MSK, which were paid in the first quarter of 2019, (b) an aggregate of \$3.4 million of license fees paid to MSK and Moffitt during the year for other CAR T immunotherapy technology, (c) the exercise of the option to license ATA190 from QIMR Berghofer and (d) clinical study, manufacturing and other outside service costs related to the Phase 1 clinical study of ATA188 for patients with PMS. We anticipate that ATA188, CAR T and other program expenses will increase in 2020, primarily driven by higher costs associated with research and manufacturing process development costs related to our CAR T programs and increased clinical study, manufacturing and other outside service costs related to the enrollment in the Phase 1b portion of our clinical study of ATA188 for patients with PMS.

Employee and overhead expenses were \$132.0 million in 2019 as compared to \$86.5 million in 2018 and \$38.3 million in 2017. The increases in 2019 and 2018 were primarily a result of higher payroll and related costs and higher facility-related expenses in support of our continuing expansion of research and development and manufacturing activities. Payroll and related costs increased by \$29.6 million in 2019 as compared to 2018 and by \$29.7 million in 2018 as compared to 2017, primarily due to increased headcount. Facility-related expenses increased by \$10.4 million in 2019 as compared to 2018, and by \$10.6 million in 2018 as compared to 2017, primarily due to higher rent, depreciation expense and IT costs to support the continued expansion of research and manufacturing process development. Professional service costs increased by \$5.6 million in 2019 as compared to 2018, and by \$7.9 million in 2018 as compared to 2017, due to our continued expansion of research and development activities. We anticipate that employee and overhead expenses will continue to increase in 2020 as we continue to expand research and development and manufacturing activities and increase average headcount to support the expansion of such activities.



*General and administrative expenses*

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

	Year ended December 31,			Increase	
	2019	2018	2017	2019 compared to 2018	2018 compared to 2017
			(in thousands)		
General and administrative	\$ 79,584	\$ 69,654	\$ 40,326	\$ 9,930	\$ 29,328

General and administrative expenses were \$79.6 million in 2019 as compared to \$69.7 million in 2018 and \$40.3 million in 2017. The increase of \$9.9 million in 2019 was primarily due to increases in compensation-related costs driven by increased headcount. The increase of \$29.3 million in 2018 was primarily due to a \$13.2 million increase in compensation-related costs driven by increased headcount and a \$17.3 million increase in professional and outside services costs. We expect that general and administrative costs will increase in 2020, primarily due to higher average headcount and other outside service costs.

## Quarterly Results of Operations Data (unaudited)

The following table sets forth our unaudited consolidated statement of operations data for each of the eight quarters in the period ended December 31, 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
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 (benefit from) income taxes	—	—	—	12
Net loss	(66,257)	(74,328)	(71,895)	(78,496)
Other comprehensive (loss) gain:				
Unrealized (loss) gain 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)

	Three months ended			
	March 31	June 30	September 30	December 31
2018	(In thousands, except per share amounts)			
Operating expenses:				
Research and development	\$ 28,460	\$ 33,387	\$ 43,355	\$ 62,255
General and administrative	13,992	19,236	16,865	19,561
Total operating expenses	42,452	52,623	60,220	81,816
Loss from operations	(42,452)	(52,623)	(60,220)	(81,816)
Interest and other income, net	1,009	1,743	1,859	1,757
Loss before provision for income taxes	(41,443)	(50,880)	(58,361)	(80,059)
Provision for (benefit from) income taxes	—	3	—	(47)
Net loss	(41,443)	(50,883)	(58,361)	(80,012)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(373)	19	56	109
Comprehensive loss	\$ (41,816)	\$ (50,864)	\$ (58,305)	\$ (79,903)
Basic and diluted net loss per common share	\$ (1.05)	\$ (1.15)	\$ (1.29)	\$ (1.75)

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common stock and preferred stock.

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 estimated offering expenses payable by us.

In February 2019, we entered into a sales agreement, or the 2019 ATM Facility, with Cowen and Company, LLC, or 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 issuance and sale of these shares by us pursuant to the 2019 ATM Facility are deemed “at the market” offerings defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, 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 2019 ATM Facility. During the 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. During January 2020, we sold an additional aggregate of 1,371,216 shares of common stock under the 2019 ATM Facility, at an average price of \$15.77 per share, for gross proceeds of \$21.6 million and net proceeds of \$21.1 million, after deducting commissions and other offering expenses payable by us.

As of December 31, 2019, we had approximately \$49.5 million of common stock remaining to be sold under the 2019 ATM Facility, and as of January 31, 2020, we had approximately \$27.9 million of common stock remaining to be sold under the 2019 ATM Facility.

In February 2020, we entered into a new sales agreement, or 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 of 1933, as amended. We will pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2020 ATM Facility.

We have incurred losses and negative cash flows from operations in each year since inception. As of December 31, 2019, we had an accumulated deficit of \$818.0 million. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products. As such, we anticipate that we will continue to incur losses the foreseeable future. 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 the equity capital markets to support our development efforts and operations, including by utilizing our ATM facilities. 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 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. We expect that existing cash, cash equivalents and short-term investments as of December 31, 2019, together with the net proceeds from our sale of common stock under the 2019 ATM Facility in January 2020, will be sufficient to fund our planned operations into the second quarter of 2021.

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

	December 31, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	\$ 74,317	\$ 60,698
Short-term investments	184,792	248,933
Total cash, cash equivalents and short-term investments	<u>\$ 259,109</u>	<u>\$ 309,631</u>

## 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,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	\$ (235,626)	\$ (179,772)	\$ (87,502)
Investing activities	60,459	(196,289)	99,909
Financing activities	188,786	357,536	20,048
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 13,619</u>	<u>\$ (18,525)</u>	<u>\$ 32,455</u>

### Operating activities

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.

Net cash used in operating activities was \$179.8 million in 2018 as compared to \$87.5 million in 2017. The increase of \$92.3 million was primarily due to a \$111.2 million increase in net loss and a \$2.6 million increase in the accretion of investment discounts, partially offset by a \$10.7 million increase stock-based compensation, a \$2.8 million increase in depreciation expense, a \$0.2 million increase in non-cash interest expense, and an increase in changes in operating assets and liabilities of \$7.8 million.

### Investing activities

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 of 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.

Net cash provided by investing activities in 2017 consisted primarily of \$296.6 million received from maturities and sales of available-for-sale securities, partially offset by \$176.5 million used to purchase available-for-sale securities and \$20.2 million used to purchase property and equipment.

### Financing activities

Net cash provided by financing activities in 2019 consisted primarily of \$140.9 million of net proceeds received from the underwritten public offering of common stock and pre-funded warrants in July 2019, \$47.7 million of net proceeds from our 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 the 2017 ATM Facility 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.

Net cash provided by financing activities in 2017 consisted of \$19.2 million of net proceeds from our 2017 ATM Facility and \$1.2 million of net proceeds from employee stock award transactions, partially offset by \$0.4 million of taxes paid related to the net share settlement of restricted stock.

## 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 significant revenue from product sales unless and until we obtain regulatory approval of 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, 2019, together with net proceeds from our 2019 ATM Facility in January 2020, will be sufficient to fund our planned operations into the second quarter of 2021. 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.

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 and costs of our ongoing and planned clinical and preclinical studies for our product candidates;
- 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 terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the cost of hiring and compensating the headcount necessary to support our business;
- 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.

## 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. The lease expires in April 2021.

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 our approximately 8,400 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, 2019:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years (in thousands)	3-5 Years	More than 5 Years
Operating lease obligations	\$ 25,380	\$ 2,867	\$ 5,350	\$ 5,276	\$ 11,887
Finance lease obligations	580	308	243	29	—
Purchase obligations (1)	29,980	17,260	12,720	—	—
Total contractual obligations	<u>\$ 55,940</u>	<u>\$ 20,435</u>	<u>\$ 18,313</u>	<u>\$ 5,305</u>	<u>\$ 11,887</u>

- (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, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, during the periods presented.

#### 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, 2019, we had total cash, cash equivalents and short-term investments of \$259.1 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 obligations of the U.S. Treasury or U.S. Treasury-guaranteed securities, do not exceed 5% of our portfolio.

**Item 8. Financial Statements and Supplementary Data**

**Index to Consolidated Financial Statements**

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	72
<a href="#">Consolidated Balance Sheets</a>	74
<a href="#">Consolidated Statements of Operations and Comprehensive Loss</a>	75
<a href="#">Consolidated Statements of Stockholders' Equity</a>	76
<a href="#">Consolidated Statements of Cash Flows</a>	77
<a href="#">Notes to Consolidated Financial Statements</a>	78

## 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 February 27, 2020 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 Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

### 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 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  
February 27, 2020

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

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

	December 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 74,317	\$ 60,698
Short-term investments	184,792	248,933
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	13,689	11,664
Total current assets	272,992	321,489
Property and equipment, net	54,176	68,576
Operating lease assets	14,007	—
Restricted cash - long-term	1,200	1,200
Other assets	567	574
Total assets	<u>\$ 342,942</u>	<u>\$ 391,839</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 7,963	\$ 3,719
Accrued compensation	14,706	10,636
Accrued research and development expenses	8,341	19,210
Other current liabilities	5,733	6,414
Total current liabilities	36,743	39,979
Operating lease liabilities - long-term	14,136	—
Other long-term liabilities	1,282	13,003
Total liabilities	52,161	52,982
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock—\$0.0001 par value, 500,000 shares authorized as of December 31, 2019 and 2018, respectively; 56,806 and 45,951 shares issued and outstanding as of December 31, 2019 and 2018, respectively	6	5
Additional paid-in capital	1,108,516	866,541
Accumulated other comprehensive income (loss)	220	(340)
Accumulated deficit	(817,961)	(527,349)
Total stockholders' equity	290,781	338,857
Total liabilities and stockholders' equity	<u>\$ 342,942</u>	<u>\$ 391,839</u>

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

	Years Ended December 31,		
	2019	2018	2017
Operating expenses:			
Research and development	\$ 216,097	\$ 167,457	\$ 81,206
General and administrative	79,584	69,654	40,326
Total operating expenses	295,681	237,111	121,532
Loss from operations	(295,681)	(237,111)	(121,532)
Interest and other income, net	4,717	6,368	2,027
Loss before provision for income taxes	(290,964)	(230,743)	(119,505)
Provision for (benefit from) income taxes	12	(44)	(14)
Net loss	\$ (290,976)	\$ (230,699)	\$ (119,491)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities	560	(189)	32
Comprehensive loss	\$ (290,416)	\$ (230,888)	\$ (119,459)
Net loss per common share:			
Basic and diluted net loss per common share	\$ (5.67)	\$ (5.27)	\$ (4.00)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	51,308	43,811	29,863

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2017	28,933	\$ 3	\$ 431,075	\$ (183)	\$ (177,159)	\$ 253,736
Issuance of common stock through ATM facilities, net of commissions and offering costs of \$844	1,350	—	19,156	—	—	19,156
RSU settlements, net of shares withheld	305	—	(357)	—	—	(357)
Issuance of common stock pursuant to employee stock awards	142	—	1,688	—	—	1,688
Stock-based compensation expense	—	—	23,100	—	—	23,100
Net loss	—	—	—	—	(119,491)	(119,491)
Unrealized gain on available-for-sale securities	—	—	—	32	—	32
Balance as of December 31, 2017	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	<u>56,806</u>	<u>\$ 6</u>	<u>\$ 1,108,516</u>	<u>\$ 220</u>	<u>\$ (817,961)</u>	<u>\$ 290,781</u>

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

	Year Ended December 31,		
	2019	2018	2017
<b>Operating activities</b>			
Net loss	\$ (290,976)	\$ (230,699)	\$ (119,491)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	51,696	33,817	23,100
Depreciation and amortization expense	7,070	3,732	956
(Accretion) amortization of investment (discounts) premiums	(1,330)	(1,885)	732
Loss on disposals of property and equipment	1,027	—	—
Non-cash operating lease expense	964	—	—
Non-cash interest expense	—	211	—
Asset retirement obligation accretion expense	71	49	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(998)	(5,764)	(784)
Operating lease assets	239	—	—
Other assets	322	(314)	2
Accounts payable	4,213	(1,958)	2,163
Accrued compensation	4,070	4,972	1,919
Accrued research and development expenses	(10,869)	15,204	1,598
Other current liabilities	(394)	2,491	1,896
Operating lease liabilities	(731)	—	—
Other long-term liabilities	—	372	407
Net cash used in operating activities	(235,626)	(179,772)	(87,502)
<b>Investing activities</b>			
Purchases of short-term investments	(270,230)	(466,489)	(176,459)
Proceeds from maturities and sales of short-term investments	336,261	306,125	296,600
Purchases of property and equipment	(5,733)	(35,925)	(20,232)
Proceeds from sale of property and equipment	161	—	—
Net cash provided by (used in) investing activities	60,459	(196,289)	99,909
<b>Financing activities</b>			
Proceeds from sale of common stock in underwritten offerings, net	140,888	293,290	—
Proceeds from issuance of common stock through ATM facilities, net	47,729	47,586	19,156
Proceeds from employee stock awards	7,350	24,691	1,249
Taxes paid related to net share settlement of restricted stock units	(6,695)	(7,503)	(357)
Principal payments on finance and capital lease obligations	(486)	(528)	—
Net cash provided by financing activities	188,786	357,536	20,048
Increase (decrease) in cash, cash equivalents and restricted cash	13,619	(18,525)	32,455
Cash, cash equivalents and restricted cash at beginning of period	62,092	80,617	48,162
Cash, cash equivalents and restricted cash at end of period	\$ 75,711	\$ 62,092	\$ 80,617
<b>Non-cash investing and financing activities</b>			
Proceeds from issuance of common stock through ATM facilities received subsequent to December 31, 2019	\$ 1,185	\$ —	\$ —
Property and equipment purchases included in accounts payable and other accrued liabilities	\$ 276	\$ 1,579	\$ 10,122
Accrued costs related to underwritten public offering	\$ 172	\$ —	\$ 160
Capitalized lease obligations	\$ —	\$ 441	\$ 9,904
Property and equipment acquired under capital leases	\$ —	\$ 191	\$ 1,076
Asset retirement costs	\$ —	\$ 88	\$ 580
Interest capitalized during construction period for build-to-suit lease arrangement	\$ —	\$ 77	\$ 264
Proceeds from options exercised received subsequent to December 31, 2017	\$ —	\$ —	\$ 439
<b>Supplemental cash flow disclosure</b>			
Cash paid for interest	\$ 50	\$ 240	\$ —
Cash paid for taxes	\$ —	\$ —	\$ —

## **1. Description of Business**

Atara Biotherapeutics, Inc. (“Atara”, “we”, “our” or “the Company”) was incorporated in August 2012 in Delaware. Atara is a leading off-the-shelf, allogeneic T-cell immunotherapy company that is developing novel treatments for patients with cancer, autoimmune and viral diseases. We have several T-cell immunotherapies in clinical development and are progressing a next-generation allogeneic chimeric antigen receptor T-cell (“CAR T”) program.

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 on public and private equity financings to fund our operations. As of December 31, 2019, we had an accumulated deficit of \$818.0 million. 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, 2019, together with net proceeds from the sale of common stock from our 2019 ATM Facility, as defined in Note 9, in January 2020, will be sufficient to fund our planned operations into the second quarter of 2021.

### **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.

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 clinical study and other accruals, lease assets and liabilities, stock-based compensation expense and income taxes. Actual results could differ materially from those estimates.

### Leases

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 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 with 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.

## **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, 2019 were not material.

## **Cash Equivalents and Short-Term Investments**

Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 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 than 90 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 or if an other-than-temporary 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 other-than-temporarily impaired, which would require us to record an 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, the financial condition of the issuer and any changes thereto, 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. Our assessment on whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are recorded to interest and other income (expense), net in the statements of operations and comprehensive loss.

## **Fair Value Measurement**

The carrying amounts of certain of our financial instruments including cash equivalents, 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 value on a recurring basis using the following hierarchy to prioritize valuation inputs, in accordance with applicable GAAP:

Level1:Quoted prices in active markets for identical assets or liabilities that we have the ability to access

Level2: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 from three 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 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.

### 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 an allocation of facility, 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 first 6% of an individual's eligible earnings, up to the annual IRS maximum. For the year ended December 31, 2019, we recorded matching contributions of approximately \$1.6 million.

### Other Current Liabilities

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

	December 31, 2019	December 31, 2018
	(in thousands)	
Accrued operating expenses	\$ 3,900	\$ 5,627
Current portion of operating lease liabilities	1,312	—
Current portion of finance and capital lease liabilities	269	587
Other accrued liabilities	252	200
Total other current liabilities	<u>\$ 5,733</u>	<u>\$ 6,414</u>

### 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, 2019 and 2018. 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 Accounting Standards Update (“ASU”) issued by the Financial Accounting Standards Board (“FASB”). ASUs not listed below were assessed and determined to be either not applicable or are expected to have minimal impact on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which was clarified and amended by the issuances of ASUs 2018-19, 2019-04, 2019-05 and 2019-11 in November 2018, April 2019, May 2019 and November 2019, respectively. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis are measured using an expected-loss model, replacing the current incurred-loss model, and recorded through an allowance for credit losses. The guidance also establishes a new impairment model for available-for-sale debt securities. We adopted the new standard and the related amendments on January 1, 2020 using a modified retrospective approach. The adoption did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued 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* (ASU 2018-15), which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal use software (and hosting arrangements that include an internal-use software license). The guidance provides criteria for determining which implementation costs to capitalize as an asset related to the service contract and which costs to expense. We adopted the new standard on January 1, 2020 using a prospective approach. We do not expect the adoption to have a material impact on our consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12), 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 pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. We early adopted the new standard on January 1, 2020. We do not expect the adoption to have a material impact on our consolidated financial statements.

## Adoption of New Accounting Pronouncements

We adopted ASU No. 2016-02, *Leases (Topic 842)*, as of January 1, 2019, using the optional transition method, which allows for the initial application of the new accounting standard at the adoption date and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the period of adoption. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification. In addition, we elected the hindsight practical expedient to determine the lease term for existing leases.

Adoption of the new standard resulted in the recording of additional operating lease assets and operating lease liabilities of \$14.3 million and \$15.3 million, respectively, as of January 1, 2019. This was partially offset by de-recognition of the build-to-suit asset and corresponding lease obligation of \$10.3 million for our Thousand Oaks manufacturing facility lease, as we did not control the building during the construction period (see Note 7). We evaluated the impact of the new standard for deferred tax accounting purposes and recorded corresponding deferred tax assets and liabilities upon adoption of ASC 842. The deferred tax assets are offset by the valuation allowance on deferred taxes. The cumulative effect adjustment to the opening balance of accumulated deficit was a decrease of \$0.4 million. The standard did not have a significant impact on our consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flow for the years ended December 31, 2019, 2018 and 2017.

We adopted ASU No. 2018-02, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for adjustments to tax effects that were originally recorded in other comprehensive income due to changes in the U.S. federal corporate income tax rate resulting from the enactment of the U.S. tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The new standard had no impact on our consolidated balance sheets as of December 31, 2019 and 2018 or our consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flow for the years ended December 31, 2019, 2018 and 2017.

### 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”), 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,		
	2019	2018	2017
Unvested RSUs	1,910,764	1,405,460	1,685,000
Vested and unvested options	6,934,262	6,276,999	5,229,648
ESPP share purchase rights	20,438	7,974	14,905
Total	<u>8,865,464</u>	<u>7,690,433</u>	<u>6,929,553</u>

#### 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, 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		<u>\$ 184,571</u>	<u>\$ 233</u>	<u>\$ (12)</u>	<u>\$ 184,792</u>

As of December 31, 2018:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
(in thousands)					
Money market funds	Level 1	\$ 38,708	\$ —	\$ —	\$ 38,708
U.S. Treasury obligations	Level 2	111,164	4	(80)	111,088
Government agency obligations	Level 2	15,206	1	(32)	15,175
Corporate debt obligations	Level 2	121,017	15	(217)	120,815
Commercial paper	Level 2	12,935	—	—	12,935
Asset-backed securities	Level 2	11,894	—	(31)	11,863
Total available-for-sale securities		310,924	20	(360)	310,584
Less amounts classified as cash equivalents		(61,651)	—	—	(61,651)
Amounts classified as short-term investments		<u>\$ 249,273</u>	<u>\$ 20</u>	<u>\$ (360)</u>	<u>\$ 248,933</u>

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

	As of December 31, 2019		As of December 31, 2018	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	\$ 214,085	\$ 214,199	\$ 287,755	\$ 287,469
Maturing in one to five years	42,993	43,100	23,169	23,115
Total available-for-sale securities	<u>\$ 257,078</u>	<u>\$ 257,299</u>	<u>\$ 310,924</u>	<u>\$ 310,584</u>

As of December 31, 2019, certain available-for-sale securities had been in a continuous unrealized loss position, each for less than twelve months. As of this date, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the respective issuers. Because we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before recovery of their amortized cost bases, which may be maturity, we do not consider these investments to be other-than-temporarily impaired at December 31, 2019. During the years ended December 31, 2019, 2018 and 2017, we did not recognize any other-than-temporary impairment losses.

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, 2019 and 2018, 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, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	\$ 74,317	\$ 60,698
Restricted cash - short-term	194	194
Restricted cash - long-term	1,200	1,200
Total cash, cash equivalents and restricted cash	<u>\$ 75,711</u>	<u>\$ 62,092</u>

## 5. Property and Equipment

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

	December 31, 2019	December 31, 2018
	(in thousands)	
Leasehold improvements	\$ 49,028	\$ 47,609
Build-to-suit asset (see Note 7)	—	10,686
Lab equipment	6,815	3,019
Machinery and equipment	3,832	2,980
Computer equipment and software	3,299	3,049
Furniture and fixtures	1,764	1,628
Construction in progress	1,116	4,682
Property and equipment, gross	65,854	73,653
Less accumulated depreciation and amortization	(11,678)	(5,077)
Property and equipment, net	<u>\$ 54,176</u>	<u>\$ 68,576</u>

Construction in progress represents capitalized costs for our manufacturing facility in Thousand Oaks, California and capitalizable costs incurred for equipment held at our facilities. Depreciation and amortization expense was \$7.1 million, \$3.7 million and \$1.0 million for the years ended December 31, 2019, 2018 and 2017, 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. In connection with the execution of the agreement, the Company paid \$4.5 million in cash to MSK.

We are required to make additional 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 later 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. In consideration for the exclusive license, the Company paid \$3.0 million in cash to QIMR Berghofer.

Under the terms of the license agreement, we possess 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 in exchange for \$3.3 million in cash, which was recorded as research and development expense in our consolidated statement of operations and comprehensive loss in the third quarter of 2016. 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 eliminate our license to certain rights related to cytomegalovirus. 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 from the National Institutes of Health in December 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 in connection with each of these licenses.

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, 2019 and 2018, there were no outstanding obligations for milestones and royalties under our license and collaboration agreements.

**Cognate Agreement** – In December 2019, Atara entered into a Commercial Manufacturing Services Agreement (the “Manufacturing Agreement”) with Cognate Bioservices, Inc. (“Cognate”) to supersede the Development and Manufacturing Agreement that was entered into with Cognate in August 2015 and amended in December 2017, May 2018, November 2018, June 2019 and November 2019. Pursuant to the Manufacturing Agreement, Cognate provides manufacturing services for certain Atara 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. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of services for at least ninety days.

## 7. Leases

We lease our corporate headquarters in South San Francisco, California under a non-cancellable lease agreement that expires in April 2021. 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. 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 approximately 90,580 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 and nine 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 and \$0.3 million for the years ended December 31, 2018 and 2017, respectively, 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 year ended December 31, 2019.

The maturities of lease liabilities under our operating and finance leases as of December 31, 2019 were as follows:

Years Ending December 31,	<u>Operating Leases</u> <u>Finance Leases</u>	
	(in thousands)	
2020	\$ 2,867	\$ 308
2021	2,740	127
2022	2,610	116
2023	2,685	29
2024	2,591	—
Thereafter	11,887	—
Total lease payments	<u>\$ 25,380</u>	<u>\$ 580</u>
Less: amount representing interest	(9,932)	(67)
Present value of lease liabilities	<u>\$ 15,448</u>	<u>\$ 513</u>
<b>Balance as of December 31, 2019</b>		
Other current liabilities	\$ 1,312	\$ 269
Operating lease liabilities	14,136	—
Other long-term liabilities	—	244
Total	<u>\$ 15,448</u>	<u>\$ 513</u>

The components of lease cost were as follows:

	<u>Year Ended</u> <u>December 31, 2019</u>	
	(in thousands)	
<b>Operating lease cost:</b>		
Operating lease cost	\$ 2,578	
Short-term lease cost	770	
Total operating lease cost	<u>\$ 3,348</u>	
<b>Finance lease cost:</b>		
Amortization expense	\$ 324	
Interest on lease liabilities	56	
Total finance lease cost	<u>\$ 380</u>	



Future minimum payments under our operating, finance and capital leases as of December 31, 2018 were as follows:

Years Ending December 31,	Operating Leases	Finance Leases	Capital Leases
	(in thousands)		
2019	\$ 1,107	\$ 934	\$ 540
2020	1,666	962	234
2021	1,555	991	29
2022	1,337	1,020	—
2023	1,375	1,051	—
Thereafter	3,122	11,458	—
<b>Total minimum payments</b>	<b>\$ 10,162</b>	<b>\$ 16,416</b>	<b>\$ 803</b>
Less: amount representing interest			(65)
Present value of capital lease obligations			738
Less: current portion			(490)
<b>Capital lease obligation, net of current portion</b>			<b>\$ 248</b>

Rent expense under operating leases for the years ended December 31, 2018 and 2017 was \$2.2 million and \$1.4 million, respectively.

Other information related to leases was as follows:

	Year Ended December 31, 2019 (in thousands, except lease term and discount rate)
<b>Supplemental Cash Flows Information</b>	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	\$ 2,346
Operating cash flows for finance leases	50
Financing cash flows for finance leases	486
Operating lease assets obtained in exchange for lease obligations:	
	\$ 838
Finance lease assets obtained in exchange for lease obligations:	
	323
<b>Weighted Average Remaining Lease Term</b>	
Operating leases	10.3 years
Finance leases	2.5 years
<b>Weighted Average Discount Rate</b>	
Operating leases	10.4%
Finance leases	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, 2018	\$	717
Accretion expense		71
Balance as of December 31, 2019	\$	788

## 8. 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, 2019 and 2018, 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 believe the fair value of these indemnification agreements is minimal. Accordingly, we did not record liabilities for these agreements as of December 31, 2019 and 2018.

### 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.

## 9. 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, 2019 and 2018.

## 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, 2019, none of the pre-funded warrants had been exercised.

## 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 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. We pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2019 ATM Facility.

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. During the fiscal year ended December 31, 2018, we sold an aggregate of 1,007,806 shares of common stock under the 2017 ATM Facility, at an average price of \$48.52 per share, for gross proceeds of \$48.9 million and net proceeds of \$47.6 million, after deducting commissions and other offering expenses payable by us. The issuance and sale of these shares by us pursuant to the 2019 ATM Facility and 2017 ATM Facility 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, 2019, we had \$49.5 million of common stock available to be sold under the 2019 ATM Facility. In January 2020, we sold an aggregate of 1,371,216 shares of common stock under the 2019 ATM Facility, at an average price of \$15.77 per share, for gross proceeds of \$21.6 million and net proceeds of \$21.1 million, after deducting commissions payable by us. As of January 31, 2020, we had \$27.9 million of common stock available to be 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 of 1933, as amended. We will pay a commission of up to 3.0% of gross sales proceeds of any common stock sold under the 2020 ATM Facility.

## 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, or 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. 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, 2019, a total of 11,935,558 shares of common stock were reserved for issuance under the 2014 EIP, of which 3,948,605 shares were available for future grant and 7,986,953 shares were subject to outstanding options and RSUs.

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. As of December 31, 2019, 1,213,760 shares of common stock were reserved for issuance under the Inducement Plan, of which 427,436 shares were available for future grant and 786,324 shares were subject to outstanding options and RSUs.

### Restricted Stock Units

The fair value of RSUs is determined as the closing stock price on the date of grant. The weighted average grant date fair value of RSUs granted during the years ended December 31, 2019, 2018 and 2017 was \$27.04, \$36.83 and \$15.07, respectively. The estimated fair value of RSUs that vested in the years ended December 31, 2019, 2018 and 2017 was \$13.8 million, \$10.8 million and \$3.7 million, respectively. As of December 31, 2019, there was \$38.0 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.1 years. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2019 was \$31.5 million.

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

	RSUs	
	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2018	1,405,460	\$ 26.94
Granted	1,591,888	\$ 27.04
Forfeited	(514,516)	\$ 30.37
Vested	(572,068)	\$ 24.16
Outstanding as of December 31, 2019	<u>1,910,764</u>	<u>\$ 26.93</u>

Under our RSU net settlement procedures, for most of our employees, we withhold shares at settlement to cover the minimum payroll withholding tax obligations. 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. During 2018, we settled 638,518 shares underlying RSUs, of which 440,503 shares underlying RSUs were net settled by withholding 190,205 shares. The value of the shares underlying RSUs withheld was \$7.5 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)
Outstanding as of December 31, 2018	6,276,999	\$ 28.15		
Granted	2,535,425	26.97		
Exercised	(347,716)	14.84		
Forfeited or expired	(1,530,446)	28.76		
Outstanding as of December 31, 2019	6,934,262	\$ 28.25	5.9	\$ 4,103
Vested and expected to vest as of				
December 31, 2019	6,934,262	\$ 28.25	5.9	\$ 4,103
Exercisable as of December 31, 2019	2,932,449	\$ 26.89	4.0	\$ 1,689

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2019 and the exercise price of outstanding, in-the-money options. As of December 31, 2019, there was \$69.7 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.8 years.

Options for 347,716, 1,051,180 and 60,125 shares of our common stock were exercised during the years ended December 31, 2019, 2018 and 2017, with an intrinsic value of \$3.8 million, \$19.2 million and \$0.2 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 to employees during the periods indicated:

	Year ended December 31,		
	2019	2018	2017
<b>Assumptions:</b>			
Expected term (years)	5.9	4.6	4.5
Expected volatility	76.1%	73.5%	71.3%
Risk-free interest rate	2.1%	2.7%	1.9%
Expected dividend yield	0.0%	0.0%	0.0%
<b>Fair Value:</b>			
Weighted-average estimated grant date fair value per share	\$ 18.06	\$ 22.96	\$ 9.01
Options granted	2,535,425	2,998,650	1,694,000
Total estimated grant date fair value	\$ 45,790,000	\$ 68,849,000	\$ 15,263,000

The estimated fair value of stock options that vested in the years ended December 31, 2019, 2018 and 2017 was \$31.6 million, \$16.2 million and \$14.0 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 \$1.3 million, \$1.2 million and \$0.6 million of expense related to the 2014 ESPP in the years ended December 31, 2019, 2018 and 2017, respectively. A total of 139,466, 109,193 and 81,922 shares were purchased under the ESPP during the years ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, there was \$0.5 million of unrecognized stock-based compensation expense related to the ESPP that is expected to be recognized by the end of second quarter of 2020.

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, 2019, there were 1,355,973 shares authorized under the 2014 ESPP.

## Reserved Shares

The following shares of common stock were reserved for future issuance as of December 31, 2019:

	<b>Total Shares Reserved</b>
2014 Equity Incentive Plan	11,935,558
2018 Inducement Plan	1,213,760
2014 Employee Stock Purchase Plan	1,002,548
Options outside the equity plans	109,666
<b>Total reserved shares of common stock</b>	<b>14,261,532</b>

## Stock-based Compensation Expense

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

	<b>Year Ended December 31,</b>		
	<b>2019</b>	<b>2018</b>	<b>2017</b>
	<b>(in thousands)</b>		
Research and development	\$ 26,773	\$ 16,211	\$ 8,778
General and administrative	24,923	17,606	14,322
<b>Total stock-based compensation expense</b>	<b>\$ 51,696</b>	<b>\$ 33,817</b>	<b>\$ 23,100</b>

## 10. Income Taxes

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

	<b>Year Ended December 31,</b>		
	<b>2019</b>	<b>2018</b>	<b>2017</b>
	<b>(in thousands)</b>		
United States	\$ (291,049)	\$ (230,765)	\$ (12,894)
Foreign	85	22	(106,611)
<b>Total loss before provision for income taxes</b>	<b>\$ (290,964)</b>	<b>\$ (230,743)</b>	<b>\$ (119,505)</b>

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,		
	2019	2018	2017
	(in thousands)		
Current provision for (benefit from) income taxes:			
Federal	\$ —	\$ (31)	\$ (14)
State	—	(15)	—
Foreign	12	2	—
Total current provision for (benefit from) income taxes	<u>\$ 12</u>	<u>\$ (44)</u>	<u>\$ (14)</u>

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

	Year Ended December 31,		
	2019	2018	2017
Federal income taxes at statutory rate	21.0%	21.0%	34.0%
Impact of stock compensation	0.1%	—	(1.5%)
Foreign income tax at different rate	—	—	(30.3%)
Impact of U.S. tax reform	—	—	(11.3%)
Non-deductible executive compensation	(0.7%)	(0.7%)	—
Capitalized research	—	7.8%	—
Other	(0.2%)	(0.6%)	(3.8%)
Change in valuation allowance	(20.2%)	(27.5%)	12.9%
Effective tax rate	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

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,	
	2019	2018
	(in thousands)	
Deferred tax assets:		
Net operating losses	\$ 162,436	\$ 91,994
Capitalized expenses	14,129	16,019
Stock-based compensation	17,573	8,578
License fees	6,870	7,380
Operating lease liabilities	4,325	—
Legal fees	1,683	1,375
Other	3,329	1,807
Total deferred tax assets	210,345	127,153
Valuation allowance	(205,249)	(127,153)
Total deferred tax assets	5,096	—
Deferred tax liabilities:		
Operating lease assets	(3,921)	—
Other	(1,175)	—
Total deferred tax liabilities	(5,096)	—
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

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, 2019 and 2018. 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 \$78.1 million for the year ended December 31, 2019 and increased by \$79.9 million for the year ended December 31, 2018.

As of December 31, 2019, we had federal and state net operating loss carryforwards for tax return purposes of \$547.7 million and \$695.4 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2032 in various amounts if not utilized. Of the \$547.7 million federal net operating losses, \$482.2 million were generated after January 1, 2018 and are not subject to expiration.

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, 2019. 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.

On December 22, 2017, the Tax Act was enacted into law. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures.

The changes in the balance of gross unrecognized tax benefits, which excludes interest and penalties, for the years ended December 31, 2017, 2018 and 2019 are as follows:

	(In thousands)
Balance as of January 1, 2017	\$ 9,285
Gross increases for tax positions related to current year	16,371
Gross increases for tax positions related to prior year	9,534
Gross decreases for tax positions related to prior year	(4,643)
Impact of change in tax rate	(496)
Balance as of December 31, 2017	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



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 \$86.0 million total unrecognized tax benefits as of December 31, 2019, no amount, if recognized, would affect the Company's effective tax rate.

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, 2019 and 2018 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.

## 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, 2019. 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, 2019 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, 2019 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, 2019. The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in its report which is included in Item 8 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, 2019, 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 identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **Report of the 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, 2019, 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, 2019, 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 sheets and related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows as of and for the year ended December 31, 2019, of the Company and our report dated February 27, 2020, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding a change in the 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**

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  
February 27, 2020

## Item 9B. Other Information

### *At the Market Offering Facility*

On February 27, 2020, we entered into a sales agreement, or the 2020 ATM Facility, with Cowen and Company, LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, par value \$0.0001 per share, or the Common Stock, having an aggregate offering price of up to \$100.0 million through Cowen, as sales agent.

Cowen may sell the Common Stock by any method that is deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Select Market or any other trading market for our common stock. Cowen will use commercially reasonable efforts to sell the Common Stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the 2020 ATM Facility, and we also have provided Cowen with customary indemnification rights.

We are not obligated to make any sales of Common Stock under the 2020 ATM Facility. The offering of shares of Common Stock pursuant to the 2020 ATM Facility will terminate upon the earlier of (i) the sale of all common stock subject to the 2020 ATM Facility or (ii) termination of the 2020 ATM Facility in accordance with its terms.

The foregoing description of the 2020 ATM Facility is qualified in its entirety by reference to the 2020 ATM Facility, a copy of which is attached hereto as Exhibit 1.1 and incorporated herein by reference.

The legal opinion of Cooley LLP relating to the shares of Common Stock being offered pursuant to the 2020 ATM Facility is filed as Exhibit 5.1 to this Annual Report on Form 10-K.

### *Cognate Agreement*

On December 24, 2019, we entered into the Commercial Manufacturing Services Agreement, or the Manufacturing Agreement, with Cognate, which was effective as of January 1, 2020. The Manufacturing Agreement supersedes the Development and Manufacturing Services Agreement, or the DSMA Agreement, with Cognate, dated August 10, 2015, as amended. The Manufacturing Agreement governs similar manufacturing services provided for under the DSMA Agreement with similar terms. Specifically, pursuant to the Manufacturing Agreement, Cognate provides process development and 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. Atara 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. The Manufacturing Agreement includes standard mutual termination rights for uncured breach or insolvency, or a force majeure event preventing the performance of services for at least ninety days.

To facilitate the entry into the Manufacturing Agreement, on November 27, 2019, we and Cognate also entered into a Fifth Amendment to the DSMA Agreement, or the DSMA Amendment, which amended the expiration date of the DSMA Agreement to December 31, 2019.

The foregoing summary descriptions of the Manufacturing Agreement and the DSMA Amendment do not purport to be complete and are qualified in their entirety by reference to the full text of the Manufacturing Agreement and the DSMA Amendment, respectively, which are filed as exhibits hereto.

### *Chief Operations Officer*

On February 27, 2020, we appointed Joseph Newell to the position of Executive Vice President, Chief Operations Officer.

Mr. Newell, age 50, has served as our Executive Vice President and Chief Technical Operations Officer since April 2017. From July 2015 to April 2017, he was Vice President, North America Manufacturing at Alexion Pharmaceuticals, Inc., a publicly traded biotechnology company. From March 2008 to July 2015, Mr. Newell served in various roles within Amgen, Inc., a publicly traded human therapeutics company, including as Executive Director and Plant Manager from August 2012 to September 2014 and Executive Director, Operations Strategic Planning from September 2014 to June 2015. He received a B.S. from California State Polytechnic University – Pomona.

In his new role, Mr. Newell will receive an annual salary of \$450,000 and will have a bonus target equal to 45% of his base salary, to be paid upon achievement of certain corporate goals. In addition, in connection with his appointment, Mr. Newell will receive 17,000 stock options and 8,500 restricted stock units.

Mr. Newell has no family relationships with any director, executive officer or person nominated or chosen by Atara to become a director or executive officer of Atara. Mr. Newell is not a party to any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

### **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 2020 annual meeting of stockholders, or 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, 2019, 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 [www.atarabio.com](http://www.atarabio.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.

A list of exhibits filed with this report or incorporated herein by reference can be found in the Exhibit Index immediately following the signature page of this Report.

## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
1.1	<a href="#">Sales Agreement, dated February 27, 2020, by and between Atara Biotherapeutics, Inc. and Cowen and Company, LLC</a>					X
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.</a>	S-1	333-196936	3.2	06/20/2014	
3.2	<a href="#">Amended and Restated Bylaws of Atara Biotherapeutics, Inc.</a>	S-1	333-196936	3.4	06/20/2014	
4.1	<a href="#">Form of Common Stock Certificate</a>	S-1/A	333-196936	4.1	07/10/2014	
4.2	<a href="#">Form of Pre-Funded Warrant</a>	8-K	001-36548	4.1	07/22/2019	
4.3	<a href="#">Investors' Rights Agreement, by and among Atara Biotherapeutics, Inc. and the stockholders named therein, dated March 31, 2014</a>	S-1	333-196936	4.2	06/20/2014	
4.4	<a href="#">Description of Securities</a>					X
5.1	<a href="#">Opinion of Cooley LLP</a>					X
10.1*	<a href="#">Amended and Restated 2014 Equity Incentive Plan</a>	10-Q	001-36548	10.2	08/08/2016	
10.2*	<a href="#">Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan</a>	S-1	333-196936	10.2	06/20/2014	
10.3*	<a href="#">Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2014 Equity Incentive Plan</a>	10-Q	001-36548	10.1	11/07/2019	
10.4*	<a href="#">2014 Employee Stock Purchase Plan</a>	S-1/A	333-196936	10.8	07/10/2014	
10.5*	<a href="#">Atara Biotherapeutics, Inc. 2018 Inducement Plan (the "Inducement Plan")</a>	10-Q	001-36548	10.1	05/08/2018	
10.6*	<a href="#">Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the Inducement Plan</a>	10-Q	001-36548	10.2	11/07/2019	
10.7*	<a href="#">Form of Stock Option Agreement and Stock Option Grant Notice under the Inducement Plan</a>	10-Q	001-36548	10.3	05/08/2018	
10.8*	<a href="#">Forms of Inducement Grant Notice and Inducement Grant Agreement</a>	10-Q	001-36548	10.3	08/07/2017	
10.9*	<a href="#">Form of Indemnification Agreement made by and between Atara Biotherapeutics, Inc. and each of its directors and executive officers</a>	S-1	333-196936	10.9	06/20/2014	
10.10*	<a href="#">Form of Employment Agreement by and between Atara Biotherapeutics, Inc. and its executive officers.</a>	10-Q	001-36548	10.4	08/01/2018	
10.11*	<a href="#">Form of Executive Employment Agreement</a>	10-Q	001-36548	10.2	08/08/2019	
10.12*	<a href="#">Executive Employment Agreement, dated May 23, 2019, by and between Pascal Touchon and Atara Biotherapeutics, Inc.</a>	8-K	001-36548	10.1	05/28/2019	
10.13†	<a href="#">Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015</a>	S-1	333-205347	10.30	06/29/2015	
10.14†	<a href="#">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</a>	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†	<a href="#">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</a>	10-Q	001-36548	10.1	08/01/2018	
10.16†	<a href="#">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 2016, as amended</a>	10-Q	001-36548	10.2	08/01/2018	
10.17+	<a href="#">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</a>	10-Q	001-36548	10.3	11/07/2019	
10.18+	<a href="#">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</a>	10-Q	001-36548	10.4	11/07/2019	
10.19†	<a href="#">Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated August 2015, as amended</a>	10-Q	001-36548	10.3	08/01/2018	
10.20+	<a href="#">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</a>	10-Q	001-36548	10.5	11/07/2019	
10.21+	<a href="#">Amendment No. 3 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated June 28, 2019</a>	10-Q	001-36548	10.6	11/07/2019	
10.22+	<a href="#">Amendment No. 4 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 4, 2019</a>					X
10.23+	<a href="#">Amendment No. 5 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 27, 2019</a>					X
10.24+	<a href="#">Commercial Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated December 24, 2019</a>					X
10.25	<a href="#">Office Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated as of December 9, 2015</a>	10-K	001-36548	10.29	03/04/2016	
10.26	<a href="#">Standard Industrial Lease by and between Thousand Oaks Industrial Portfolio, LLC and Atara Biotherapeutics, Inc. dated February 6, 2017</a>	10-Q	001-36548	10.1	05/04/2017	
21.1	<a href="#">List of Subsidiaries</a>					X
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm</a>					X
23.2	<a href="#">Consent of Cooley LLP (included in Exhibit 5.1)</a>					X
24.1	<a href="#">Power of Attorney (included on signature page)</a>					
31.1	<a href="#">Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13A-14A and 15D-14A</a>					X

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
31.2	<a href="#">Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13A-14A and 15D-14A</a>					X
32.1(1)	<a href="#">Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 USC Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002</a>					X
101.INS	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 Schema Document					X
101.CAL	Inline XBRL Calculation Linkbase Document					X
101.DEF	Inline XBRL Definition Linkbase Document					X
101.LAB	Inline XBRL Labels Linkbase Document					X
101.PRE	Inline XBRL Presentation Linkbase Document					X
104	The cover page from the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, 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 immaterial and would be competitively harmful 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 27th day of February, 2020.

### 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
<u>/s/ Pascal Touchon</u> Pascal Touchon	President, Chief Executive Officer and Director <i>(principal executive officer)</i>	February 27, 2020
<u>/s/ Utpal Koppikar</u> Utpal Koppikar	Chief Financial Officer <i>(principal financial and accounting officer)</i>	February 27, 2020
<u>/s/ Roy D. Baynes</u> Roy D. Baynes, M.D., Ph.D.	Director	February 27, 2020
<u>/s/ Eric Dobmeier</u> Eric Dobmeier	Director	February 27, 2020
<u>/s/ Matthew K. Fust</u> Matthew K. Fust	Director	February 27, 2020
<u>/s/ Carol G. Gallagher</u> Carol G. Gallagher, Pharm.D.	Director	February 27, 2020
<u>/s/ William Heiden</u> William Heiden	Director	February 27, 2020
<u>/s/ Beth Seidenberg</u> Beth Seidenberg, M.D.	Director	February 27, 2020

ATARA BIOTHERAPEUTICS, INC.

\$100,000,000

COMMON STOCKSALES AGREEMENT

February 27, 2020

Cowen and Company, LLC  
599 Lexington Avenue  
New York, NY 10022

Ladies and Gentlemen:

Atara Biotherapeutics, Inc., a Delaware corporation (the "**Company**"), confirms its agreement (this "**Agreement**") with Cowen and Company, LLC ("**Cowen**"), as follows:

1. **Issuance and Sale of Shares.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through Cowen, acting as agent and/or principal, shares of the Company's common stock, par value \$0.0001 per share (the "**Common Stock**"), having an aggregate offering price of up to \$100,000,000 (the "**Placement Shares**"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this **Section 1** on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through Cowen will be effected pursuant to the Registration Statement (as defined below) filed by the Company with the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission a registration statement on Form S-3 (File No. 333-223262), including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference, to the extent provided for under Form S-3, documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). The Company has prepared a prospectus supplement specifically relating to the Placement Shares (the "**Prospectus Supplement**") to the base prospectus included as part of such registration statement. The Company has furnished to Cowen, for use by Cowen, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, as amended when it became effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act, is herein called the "**Registration Statement.**" The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus

Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any “issuer free writing prospectus,” as defined in Rule 433 of the Securities Act (“**Rule 433**”), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.” Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval System or any successor thereto (collectively, “**EDGAR**”).

2. **Placements.** Each time that the Company wishes to issue and sell the Placement Shares hereunder (each, a “**Placement**”), it will notify Cowen by email notice (or other method mutually agreed to in writing by the parties) (a “**Placement Notice**”) containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in **Section 3**) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from Cowen set forth on **Schedule 2**, as such **Schedule 2** may be amended from time to time. The Placement Notice shall be effective upon receipt by Cowen unless and until (i) in accordance with the notice requirements set forth in **Section 4**, Cowen declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares have been sold, (iii) in accordance with the notice requirements set forth in **Section 4**, the Company suspends or terminates the Placement Notice, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of **Section 11**. The amount of any discount, commission or other compensation to be paid by the Company to Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in **Schedule 3**. It is expressly acknowledged and agreed that neither the Company nor Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Cowen and Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. **Sale of Placement Shares by Cowen.** Subject to the terms and conditions herein set forth, upon the Company’s issuance of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, Cowen, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The Nasdaq Global Select Market (“**Nasdaq**”) to sell such Placement Shares up to the amount specified in such Placement Notice, and otherwise in accordance with the terms of such Placement Notice. Cowen will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the

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Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company. Cowen may sell Placement Shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act, including without limitation sales made through Nasdaq or on any other existing trading market for the Common Stock. Cowen shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that Cowen will be successful in selling Placement Shares, and (ii) Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by Cowen to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this Section 3. For the purposes hereof, “**Trading Day**” means any day on which the Company’s Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

4. Suspension of Sales.

(a) The Company or Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 2), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party’s obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this Section 4 shall be effective against the other unless it is made to one of the individuals named on Schedule 2 hereto, as such schedule may be amended in writing from time to time.

(b) Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and Cowen agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares, and (iii) Cowen shall not be obligated to sell or offer to sell any Placement Shares.

(c) If either Cowen or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, it shall promptly notify the other party, and Cowen may, at its sole discretion, suspend sales of the Placement Shares under this Agreement.

(d) The Registration Statement became effective upon filing with the Securities and Exchange Commission. Notwithstanding any other provision of this Agreement, during any period in which the Registration Statement is no longer effective under the Securities Act, the Company shall promptly notify Cowen, the Company shall not request the sale of any Placement Shares, and Cowen shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2<sup>nd</sup>) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “**Settlement Date**” and the first such settlement date, the “**First Delivery Date**”). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the “**Net Proceeds**”) will be equal to the aggregate sales price received by Cowen at which such Placement Shares were sold, after deduction for (i) Cowen’s commission, discount or other compensation for such sales

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payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to Cowen hereunder pursuant to Section 7(g) (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Cowen's or its designee's account (*provided* Cowen shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System ("DWAC") or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. Cowen will be responsible for providing DWAC instructions or instructions for delivery by other means with respect to the Placement Shares being sold. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date (other than as a result of a failure by Cowen to provide true and correct instructions for delivery), the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Company Indemnification) hereto, it will (i) hold Cowen harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to Cowen any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, Cowen that as of the date of this Agreement (or, in the case of paragraph (b) below, as of the date the Registration Statement initially became effective or, if later, as of the date the Registration Statement was amended or deemed amended), each Representation Date (as defined in Section 7(m)), each date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder:

(a) Compliance with Registration Requirements. The Registration Statement became effective upon filing with the Commission. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No order suspending the effectiveness of the Registration Statement is in effect and no proceedings for that purpose have been instituted or are pending or, to the knowledge of the Company, contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act and is and has been at all relevant times a "well-known seasoned issuer" as defined in Rule 405 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements of General Instruction I.B.1 of Form S-3.

(b) Incorporated Documents. The documents incorporated by reference in the Registration Statement and the Prospectus, when they became effective or were filed with the Commission, as the case may be, conformed in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable, and none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; and any further documents so filed and incorporated by reference in the Registration Statement or the Prospectus, when such documents become effective or are filed with the Commission, as the case may be, will conform in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

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(c) Not an Ineligible Issuer. The Company currently is not an “ineligible issuer,” as defined in Rule 405 of the rules and regulation of the Commission. The Company agrees to notify Cowen promptly upon the Company becoming an “ineligible issuer.”

(d) Distribution of Offering Material By the Company. The Company has not distributed and will not distribute, prior to the completion of Cowen’s distribution of the Placement Shares, any offering material in connection with the offering and sale of the Placement Shares other than the Prospectus or the Registration Statement.

(e) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification and contribution hereunder may be limited by applicable law and public policy considerations and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(f) Placement Shares. The Placement Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered and paid for as provided herein, will be duly authorized and validly issued, fully paid and nonassessable.

(g) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(h) No Material Adverse Change. Except as otherwise disclosed in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, taken as a whole, (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business; and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for regular quarterly dividends publicly announced by the Company or dividends paid to the Company or other subsidiaries, by any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(i) Independent Accountants. Deloitte & Touche LLP, which has expressed its opinion with respect to certain financial statements of the Company and its subsidiaries contained or incorporated by reference in the Registration Statement and the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the rules and regulations of the Commission thereunder.

(j) Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries included or incorporated by reference in the Registration Statement and the Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly the consolidated financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in accordance with generally accepted accounting principles (“**GAAP**”) in the United States applied on a consistent basis throughout the periods covered thereby, and any supporting schedules included or

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incorporated by reference in the Registration Statement present fairly the information required to be stated therein; and the other financial information included or incorporated by reference in the Registration Statement and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly the information shown thereby in the Registration Statement and the Prospectus have been prepared in accordance with the applicable requirements of the Securities Act and the Exchange Act, as applicable.

(k) Organization and Good Standing. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware, with corporate power and authority to own its properties and conduct its business as described in the Registration Statement and the Prospectus, and has been duly qualified as a foreign corporation for the transaction of business and is in good standing under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, except where the failure to be so qualified or be in good standing would not individually or in the aggregate have a material adverse effect on the current or future financial position, stockholders' equity or results of operations of the Company and its subsidiaries, taken as a whole (a "**Material Adverse Effect**"); and each subsidiary of the Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of its jurisdiction of incorporation.

(l) Capitalization. All of the outstanding shares of capital stock of the Company have been duly authorized; the authorized equity capitalization of the Company is as set forth in the Prospectus; all outstanding shares of capital stock of the Company are validly issued, fully paid and nonassessable; all outstanding shares of capital stock of the Company conform, and the Placement Shares, when they have been delivered and paid for in accordance with this Agreement, will conform, in all material respects to the information thereof in the Prospectus; the stockholders of the Company have no preemptive rights with respect to the Placement Shares; and none of the outstanding shares of capital stock of the Company have been issued in violation of any preemptive or similar rights of any security holder.

(m) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its Certificate of Incorporation, By-laws or similar organizational documents, (ii) in default in the performance or observance of any material obligation, agreement, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which it is a party or by which it or any of its properties may be bound, or (iii) in violation of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties except in the case of (ii) or (iii) for such defaults as would not, individually or in the aggregate, have a Material Adverse Effect.

(n) No Conflicts. The issue and sale of the Placement Shares and the compliance by the Company with this Agreement and the consummation of the transactions herein contemplated will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, (i) any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (ii) the Certificate of Incorporation or By-laws of the Company, or (iii) any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties; except in the case of (i) and (iii) for such violations that would not individually or in the aggregate have a Material Adverse Effect; and no consent, approval, authorization, order, registration or qualification of or with any such court or governmental agency or body is required for the issue and sale of the Placement Shares or the consummation by the Company of the transactions contemplated by this Agreement, except for the registration under the Securities Act of the Placement Shares, the approval by the Financial Industry Regulatory Authority ("**FINRA**") of the underwriting terms and arrangements and such consents, approvals, authorizations,

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registrations or qualifications as may be required under state securities or Blue Sky laws in connection with the purchase and distribution of the Placement Shares by Cowen.

(o) Legal Proceedings. Except as described in the Registration Statement and the Prospectus, there are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings (“**Actions**”) pending to which the Company or any of its subsidiaries is or may be a party or, to the knowledge of the Company, to which any property of the Company or any of its subsidiaries is or may be the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, could reasonably be expected to have a Material Adverse Effect; no such Actions are threatened or, to the knowledge of the Company, contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending Actions that are required under the Securities Act to be described in the Registration Statement or the Prospectus that are not so described in the Registration Statement and the Prospectus and (ii) there are no statutes, regulations or contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement or described in the Registration Statement or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement and the Prospectus.

(p) Intellectual Property. Except as disclosed in the Registration Statement and the Prospectus, the Company and its subsidiaries own, possess, license or have an exclusive option to license adequate rights to use all patents, trademarks, service marks, trade names, copyrights, domain names, licenses, approvals, technology and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) and other intellectual property rights, including registrations and applications for registration thereof (collectively, “**Intellectual Property Rights**”) used or held to be used for the conduct of the Company’s business now conducted and as proposed in the Registration Statement and the Prospectus to be conducted, except where the failure to own, possess or license such Intellectual Property Rights would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as disclosed in the Registration Statement and the Prospectus and to the Company’s knowledge: (i) neither the Company nor any of its subsidiaries has materially infringed, misappropriated or otherwise violated the Intellectual Property Rights of any third party, and neither the manufacture of, nor the use or sale of, any of the product candidates described in the Registration Statement and the Prospectus will materially infringe or otherwise violate the Intellectual Property Rights of any third party and (ii) there are no rights of third parties to any of the Intellectual Property Rights owned by or exclusively licensed to the Company or any of its subsidiaries. Except as would not, individually or in aggregate, if determined adversely to the Company or any of its subsidiaries, reasonably be expected to have a Material Adverse Effect, there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by any third party (i) challenging the Company’s or any of its subsidiaries’ rights in or to any of the Company’s Intellectual Property Rights; (ii) alleging that the Company or any of its subsidiaries have infringed, misappropriated or otherwise violated any Intellectual Property Rights of any third party; or (iii) challenging the validity, scope or enforceability of any Intellectual Property Rights owned or exclusively licensed to the Company or any of its subsidiaries, and in the case of each of (i), (ii) and (iii), the Company is unaware of any facts that would form a reasonable basis for any such action, suit, proceeding or claim. To the Company’s knowledge, there is no infringement, misappropriation, breach or default by others of any Intellectual Property Rights owned by or exclusively licensed to the Company or any of its subsidiaries, and all Intellectual Property Rights owned by or licensed to the Company or any of its subsidiaries are valid and enforceable, except as would not reasonably be expected, individually or in aggregate, to have a Material Adverse Effect. The Company and its subsidiaries have at all times taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of all Intellectual Property Rights, the value of which to the Company and to its subsidiaries is contingent upon maintaining the confidentiality thereof. All founders, current and former employees and consultants involved in the development of the Intellectual Property Rights for the Company or any of its subsidiaries have signed confidentiality and invention assignment agreements with the Company or any of

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its subsidiaries pursuant to which the Company or any of its subsidiaries either (i) has obtained ownership of and is the exclusive owner of such Intellectual Property Rights, or (ii) has obtained a valid and unrestricted right to exploit such Intellectual Property Rights, sufficient for the conduct of the business as currently conducted and as proposed in the Registration Statement and the Prospectus to be conducted.

(q) No Undisclosed Relationships. No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, stockholders, customers, suppliers or other affiliates of the Company or any of its subsidiaries, on the other, that is required by the Securities Act to be described in each of the Registration Statement and the Prospectus and that is not so described in such documents.

(r) Investment Company Act. The Company is not and, after receipt of payment for the Placement Shares and the application of the proceeds thereof as described in the Prospectus, will not be an “investment company” as defined in the Investment Company Act of 1940, as amended (the “**Investment Company Act**”).

(s) Taxes. The Company and its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement (taking into account applicable extensions) (except where the failure to file would not, individually or in the aggregate, have a Material Adverse Effect) and have paid all taxes required to be paid thereon (except for cases in which the failure to pay would not have a Material Adverse Effect, or, except as currently being contested in good faith and for which reserves required by U.S. GAAP have been created in the financial statements of the Company), and no tax deficiency has been determined adversely to the Company or any of its subsidiaries which has had (nor has the Company nor any of its subsidiaries received any notice of any tax deficiency from any taxing authority which is reasonably expected to be determined adversely to the Company or its subsidiaries and which is reasonably expected to have) a Material Adverse Effect.

(t) Licenses and Permits. The Company possesses all certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct its business as described in the Prospectus, including, without limitation, from the U.S. Food and Drug Administration (“**FDA**”) and equivalent foreign regulatory authorities, other than those the failure to possess or own would not reasonably be expected to result in a Material Adverse Effect, and the Company has not received any written notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit, which, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect, except as described in the Registration Statement and the Prospectus.

(u) Compliance with the FDA. The Company has operated and currently is in compliance with all applicable rules, regulations and policies of the FDA, except where the failure to so operate or be in compliance would not reasonably be expected to have a Material Adverse Effect.

(v) Clinical Trials. Any clinical trials and human studies conducted by the Company and, to the knowledge of the Company, any clinical trials and human studies conducted on behalf of the Company or in which the Company has participated were and, if still pending, are being conducted in accordance with standard medical and scientific research procedures and any applicable rules, regulations and policies of the jurisdiction in which such trials and studies are being conducted, except where the failure to be so conducted would not reasonably be expected to have a Material Adverse Effect.

(w) Disclosure Controls. The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that material

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information relating to the Company and its subsidiaries is made known to the Company's principal executive officer and principal financial officer by others within those entities; and such disclosure controls and procedures are effective.

(x) Accounting Controls. The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by the Company's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP and, except as disclosed in the Registration Statement and the Prospectus, the Company is not aware of any material weaknesses in its internal control over financial reporting (it being understood that, as of the date hereof, the Company is not required to comply with Section 404 of the Sarbanes Oxley Act of 2002). Except as disclosed in the Registration Statement and the Prospectus, since the date of the latest audited financial statements included or incorporated by reference in the Registration Statement and the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting

(y) No Unlawful Payments. None of the Company, nor any of Nina Biotherapeutics, Inc., Pinta Biotherapeutics, Inc. or Santa Maria Biotherapeutics, Inc. (collectively, the "**Predecessor Entities**"), nor any of their respective subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person associated with or acting on behalf of the Company, the Predecessor Entities or any of their subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(z) Compliance with Anti-Money Laundering Laws. The operations of the Company, the Predecessor Entities and their subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency having jurisdiction over the Company, the Predecessor Entities or any of their subsidiaries (collectively, the "**Anti-Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

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(aa) No Conflicts with Sanctions Laws. Neither the Company nor any of its subsidiaries, nor, to the knowledge of the Company, any directors, officers, employees, agent, affiliate of the Company or any of its subsidiaries is currently the subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury (“**OFAC**”); and the Company will not directly or indirectly use the proceeds of the offering of the Placement Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(bb) No Registration Rights. Except such rights as have been validly waived and that are described in each of the Registration Statement and the Prospectus, no person has the right to require the Company or any of its subsidiaries to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Placement Shares.

(cc) No Stabilization. The Company has not taken, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Placement Shares.

(dd) Statistical and Market Data. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included or incorporated by reference in each of the Registration Statement and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.

(ee) No Reliance. The Company has not relied upon Cowen or legal counsel for Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(ff) Brokers. Except for Cowen, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder’s fee or other fee or commission as a result of any transactions contemplated by this Agreement.

Any certificate signed by an officer of the Company and delivered to Cowen or to counsel for Cowen in connection with this Agreement shall be deemed to be a representation and warranty by the Company to Cowen as to the matters set forth therein.

The Company acknowledges that Cowen and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with Cowen that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will prepare and file with the Commission, promptly upon Cowen’s reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in Cowen’s reasonable opinion, may be necessary or advisable

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in connection with the distribution of the Placement Shares by Cowen (*provided, however*, that the failure of Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement, *provided, further*, that the only remedy Cowen shall have with respect to the failure to make such filing (other than Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Cowen within a reasonable period of time before the filing and Cowen has not reasonably objected thereto (*provided, however*, that (A) the failure of Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement and *provided, further*, that (B) the only remedy Cowen shall have with respect to the failure by the Company to provide Cowen with such copy or the filing of such amendment or supplement despite Cowen's objection (other than Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement) and the Company will furnish to Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act, and (v) prior to the termination of this Agreement, the Company will notify Cowen if at any time the Registration Statement shall no longer be effective as a result of the passage of time pursuant to Rule 415 under the Securities Act, due to the Company no longer qualifying as a "well-known seasoned issuer" pursuant to Rule 405 and Form S-3 or otherwise.

(b) Notice of Commission Stop Orders. The Company will advise Cowen, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates (taking into account any extensions available under the Exchange Act) all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending

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sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to Cowen and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Cowen may from time to time reasonably request and, at Cowen's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to furnish any document (other than the Prospectus) to Cowen to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay all expenses incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (*provided, however*, that any fees or disbursements of counsel for Cowen in connection therewith shall be paid by Cowen except as set forth in (vii) and (viii) below), (iv) the printing and delivery to Cowen of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, (vii) any stamp or transfer taxes in connection with the original sale and issuance of the Placement Shares, and (viii) the reasonable fees and disbursements of Cowen's counsel in an amount not to exceed \$50,000.

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for five (5) Trading Days following the termination of any Placement Notice given hereunder, the Company shall provide Cowen notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options to purchase shares of Common Stock or any other equity awards, or Common Stock issuable upon the exercise of

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options or other equity awards pursuant to any stock option, stock bonus, employee stock purchase or other stock plan or arrangement described in the Prospectus, (ii) the issuance of securities in connection with any joint venture, commercial, strategic or collaborative relationship, acquisition, merger or sale or purchase of assets, (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to Cowen in advance or (iv) any shares of common stock issuable upon the exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other rights in effect or outstanding. Notwithstanding the foregoing provisions, nothing herein shall be construed to restrict the Company's ability, or require the Company to provide notice to Cowen, to file a registration statement under the Securities Act.

(j) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to Cowen pursuant to this Agreement.

(k) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as Cowen may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act, which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through Cowen, the Net Proceeds to the Company and the compensation payable by the Company to Cowen with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(m) Representation Dates; Certificate. On or prior to the First Delivery Date and each time the Company (i) amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(l) of this Agreement) by means of a post-effective amendment, sticker, or supplement filed after the date hereof but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) files an annual report on Form 10-K under the Exchange Act; (iii) files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) files a report on Form 8-K containing amended financial information (other than an earnings release or other information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144 under the Exchange Act) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Representation Date**"); the Company shall furnish Cowen with a certificate, in the form attached hereto as Exhibit 7(m), within five (5) Trading Days of any Representation Date if requested by Cowen. The requirement to provide a certificate under this Section 7(m) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date; *provided, however*, that such waiver shall not apply for any Representation Date on which the Company files its annual report on Form 10-K.

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Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide Cowen with a certificate under this Section 7(m), then before the Company delivers the Placement Notice or Cowen sells any Placement Shares, the Company shall provide Cowen with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) Legal Opinion. (i) On or prior to the First Delivery Date, the Company shall cause to be furnished to Cowen a written opinion of Cooley LLP, or other counsel satisfactory to Cowen (“**Company Counsel**”), in form and substance reasonably satisfactory to Cowen and its counsel, dated the date that the opinion is required to be delivered, and (ii) within the later of (A) five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable and (B) the date a Placement Notice is first delivered by the Company following such Representation Date, the Company shall cause to be furnished to Cowen a negative assurance letter of Company Counsel, or other counsel satisfactory to Cowen, in form and substance reasonably satisfactory to Cowen and its counsel, dated the date that the opinion is required to be delivered; *provided, however*, that the Company shall not be required to furnish Cowen any such negative assurance letter if Davis Polk & Wardwell LLP or other counsel satisfactory to Cowen (“**Cowen Counsel**”) does not also concurrently deliver a negative assurance letter to Cowen dated as of such date, which negative assurance letter of Cowen Counsel shall cover statements substantially similar to those covered by such negative assurance letter of Company Counsel.

(o) Comfort Letter. On or prior to the First Delivery Date and within the later of (A) five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, and (B) the date a Placement Notice is first delivered by the Company following a Representation Date, the Company shall cause its independent accountants to furnish Cowen a letter (the “**Comfort Letter**”), dated the date the Comfort Letter is delivered, in form and substance satisfactory to Cowen, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters” to Cowen in connection with registered public offerings (the first such letter, the “**Initial Comfort Letter**”) and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Common Stock to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than Cowen; *provided, however*, that the Company may bid for and purchase shares of its common stock in accordance with Rule 10b-18 under the Exchange Act.

(q) Insurance. The Company and its subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

(r) Compliance with Laws. The Company and each of its subsidiaries will use commercially reasonable efforts to maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause

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their businesses to be conducted, in substantial compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations could not reasonably be expected to result in a Material Adverse Effect.

(s) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an “investment company,” as such term is defined in the Investment Company Act, assuming no change in the Commission’s current interpretation as to entities that are not considered an investment company.

(t) Securities Act and Exchange Act. The Company will use its best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.

(u) No Offer to Sell. Other than the Prospectus or a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and Cowen in its capacity as principal or agent hereunder, neither Cowen nor the Company (including its agents and representatives, other than Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(v) Sarbanes-Oxley Act. The Company and its subsidiaries will use their best efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.

8. Conditions to Cowen’s Obligations. The obligations of Cowen hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by Cowen of a due diligence review satisfactory to Cowen in its reasonable judgment, and to the continuing satisfaction (or waiver by Cowen in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will

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not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Cowen's reasonable opinion is material, or omits to state a fact that in Cowen's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Effect or any development that could reasonably be expected to result in a Material Adverse Effect, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of Cowen (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Company Counsel Legal Opinion. Cowen shall have received the opinion and negative assurance letters of Company Counsel required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such opinion and negative assurance letter is required pursuant to Section 7(n).

(f) Cowen Counsel Legal Opinion. Cowen shall have received from Cowen Counsel, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as Cowen may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) Comfort Letter. Cowen shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(h) Representation Certificate. Cowen shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(i) Secretary's Certificate. On or prior to the First Delivery Date, Cowen shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to Cowen and its counsel.

(j) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq.

(k) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to Cowen such appropriate further information, certificates and documents as Cowen may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish

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Cowen with such conformed copies of such opinions, certificates, letters and other documents as Cowen shall have reasonably requested.

(l) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(m) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice.

(n) No Termination Event. There shall not have occurred any event that would permit Cowen to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless Cowen, the directors, officers, partners, employees and agents of Cowen and each person, if any, who (i) controls Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with Cowen from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading or (z) any breach by any of the indemnifying parties of any of their respective representations, warranties and agreements contained in this Agreement; *provided, however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission, or alleged untrue statements or omissions, made in reliance upon and in conformity with the Agent's Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Cowen Indemnification. Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.

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(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or Cowen, the Company and Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than Cowen, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and Cowen may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company

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on the one hand and Cowen on the other. The relative benefits received by the Company on the one hand and Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by Cowen (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and Cowen, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of Cowen, will have the same rights to contribution as that party, and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) Cowen shall have the right by giving notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Effect, or any development that could reasonably be expected to result in a Material Adverse Effect has occurred that, in the reasonable judgment of Cowen, may materially impair the ability of Cowen to sell the Placement Shares hereunder, (ii) the Company shall have

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failed, refused or been unable to perform any agreement on its part to be performed hereunder; *provided, however*, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under Sections 7(m), 7(n), or 7(o), Cowen's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than thirty (30) days from the date such delivery was required; or (iii) any other condition of Cowen's obligations hereunder is not fulfilled, or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Cowen elects to terminate this Agreement as provided in this Section 11(a), Cowen shall provide the required notice as specified in Section 12 (Notices).

(b) The Company shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) Cowen shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through Cowen on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by Cowen or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to Cowen, shall be delivered to Cowen at Cowen and Company, LLC, 599 Lexington Avenue, 27<sup>th</sup> Floor, New York, NY 10022, fax no. 646-562-1124, Attention: General Counsel; or if sent to the Company, shall be delivered to Atara Biotherapeutics, Inc., 611 Gateway Blvd., Suite 900, South San Francisco, California 94080; attention: CFO and General Counsel with a copy to Cooley LLP, 101 California Street, 5<sup>th</sup> Floor, San Francisco, California 94111; fax no. 415-693-2222, attention: Carlton Fleming. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original

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to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided, however*, that Cowen may assign its rights and obligations hereunder to an affiliate of Cowen without obtaining the Company's consent, so long as such affiliate is a registered broker-dealer.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

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17. Waiver of Jury Trial. The Company and Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) Cowen has been retained solely to act as sales agent in connection with the sale of the Placement Shares and that no fiduciary, advisory or agency relationship between the Company and Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether Cowen has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile transmission.

20. Definitions. As used in this Agreement, the following term has the meaning set forth below:

(a) “**Applicable Time**” means the date of this Agreement, each Representation Date, the date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder.

(b) “**Agent’s Information**” means, solely the following information in the Prospectus Supplement: the seventh and eighth paragraphs under the caption “Plan of Distribution” in the Prospectus Supplement.

**[Remainder of Page Intentionally Blank]**

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If the foregoing correctly sets forth the understanding between the Company and Cowen, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and Cowen.

Very truly yours,

**COWEN AND COMPANY, LLC**

By: /s/ Michael Murphy  
Name: Michael Murphy  
Title: Managing Director

**ACCEPTED as of the date  
first-above written:**

**ATARA BIOTHERAPEUTICS, INC.**

By: /s/ Utpal Koppikar  
Name: Utpal Koppikar  
Title: Chief Financial Officer

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**FORM OF PLACEMENT NOTICE**

From: [ ]  
Cc: [ ]  
To: [ ]  
Subject: Cowen at the Market Offering—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Atara Biotherapeutics, Inc. (the “Company”), and Cowen and Company, LLC (“Cowen”) dated February 27, 2020 (the “Agreement”), I hereby request on behalf of the Company that Cowen sell up to [ ] shares of the Company’s common stock, par value \$0.0001 per share, at a minimum market price of \$[ ] per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold][the aggregate sales price of the shares reaches \$[ ]].

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The Company:

- Pascal Touchon
- Utpal Koppikar

The Agent:

- Mike Murphy
  - Bill Follis
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**Compensation**

Cowen shall be paid compensation up to 3% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

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**OFFICER CERTIFICATE**

The undersigned, the duly qualified and elected \_\_\_\_\_, of Atara Biotherapeutics, Inc. ("**Company**"), a Delaware corporation, does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated \_\_\_\_\_ February 27, 2020 (the "**Sales Agreement**") between the Company and Cowen and Company, LLC, that to the best of the knowledge of the undersigned.

- (i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and
  
- (ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

By:  
Name:  
Title:

Date:

**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES  
EXCHANGE ACT OF 1934**

*Atara Biotherapeutics, Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock. The following summary of the terms of our common stock is based upon our amended and restated certificate of incorporation and our amended and restated bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. We encourage you to read our amended and restated certificate of incorporation and our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for more information. We also provide a summary of our preferred stock and our warrants, neither of which is registered under Section 12 of the Exchange Act.*

**DESCRIPTION OF CAPITAL STOCK**

**General**

Our amended and restated certificate of incorporation provides for one class of common stock. In addition, our amended and restated certificate of incorporation authorizes shares of undesignated preferred stock, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

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.

Our board of directors may issue additional shares of capital stock authorized by our amended and restated certificate of incorporation without stockholder approval, subject to obtaining stockholder approval to the extent required by the listing standards of the The Nasdaq Stock Market (the "Nasdaq") or our amended and restated certificate of incorporation.

**Common Stock**

***Voting Rights***

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, on any matter that is submitted to a vote of our stockholders, holders of our common stock are entitled to one vote per share.

We have not provided for cumulative voting for the election of directors in our amended and restated certificate of incorporation.

***Economic Rights***

*Dividends.* Subject to preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available therefor.

*Liquidation.* In the event that we liquidate, dissolve or wind up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock.

*Rights and preferences.* Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the

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holders of shares of any series of preferred stock that we may designate in the future.

*Fully paid and nonassessable.* All of our outstanding shares of Common Stock are fully paid and nonassessable.

### **Preferred Stock**

Our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with financings, possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, discouraging or preventing a change in control of our company, may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock, and may reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation.

### **Warrants**

In July 2019, we issued and sold 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. As of December 31, 2019, none of the pre-funded warrants had been exercised.

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. Per the terms of the warrant agreement, a holder of 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%.

### **Anti-Takeover Provisions**

#### ***Anti-Takeover Statute***

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

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
  - upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
  - on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock that is not owned by the interested stockholder.
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In general, Section 203 defines business combination to include the following:

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

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers, or other takeover or change in control attempts of us may be discouraged or prevented.

#### ***Anti-Takeover Effects of Certain Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws***

Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent. A special meeting of stockholders may be called by the majority of our whole board of directors, our chief executive officer or the chairman of the board of directors.

Our amended and restated certificate of incorporation provides for our board of directors to be divided into three classes, with staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Stockholders have no cumulative voting rights, and the stockholders representing a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election.

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

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

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These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

#### **Choice of Forum**

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

#### **Listing on the Nasdaq Global Select Market**

Our common stock is listed on the Nasdaq Global Select Market under the symbol "ATRA."

Carlton Fleming  
+1 650 843 5865  
cfleming@cooley.com

February 27, 2020

Atara Biotherapeutics, Inc.  
611 Gateway Blvd., Suite 900  
South San Francisco, CA 94080

Ladies and Gentlemen:

We have acted as counsel to Atara Biotherapeutics, Inc., a Delaware corporation (the "**Company**"), in connection with the sale of shares of its common stock, par value \$0.0001 per share, having an aggregate offering price of up to \$100.0 million (the "**Shares**") pursuant to the Registration Statement on Form S-3 (File No. 333-223262) (the "**Registration Statement**") filed with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Act**"), the prospectus included within the Registration Statement (the "**Base Prospectus**") and the prospectus supplement dated February 27, 2020 to be filed with the Commission pursuant to Rule 424(b) promulgated under the Act (the "**Prospectus Supplement**"). The Base Prospectus and the Prospectus Supplement are collectively referred to as the "**Prospectus**." The Shares are to be sold by the Company in accordance with that certain Sales Agreement, dated February 27, 2020, by and between the Company and Cowen and Company, LLC (the "**Agreement**"), as described in the Prospectus.

In connection with this opinion, we have examined and relied upon the Registration Statement and the Prospectus, the Agreement, the Company's Amended and Restated Certificate of Incorporation, the Company's Amended and Restated Bylaws, each as currently in effect, and the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. In rendering this opinion, we have assumed the genuineness and authenticity of all signatures on original documents; the genuineness and authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; the accuracy, completeness and authenticity of certificates of public officials, and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not sought independently to verify such matters.

We have assumed (i) that each sale of Shares will be duly authorized by the Board of Directors of the Company, a duly authorized committee thereof or a person or body pursuant to an authorization granted in accordance with Section 152 of the General Corporation Law of the State of Delaware (the "**DGCL**"), (ii) that no more than 17,985,610 Shares will be sold under the Agreement and (iii) that the price at which the Shares are sold will equal or exceed the par value of the Shares. We express no opinion to the extent that future issuances of securities of the Company and/or anti-dilution adjustments to outstanding securities of the Company cause the number of shares of the Company's common stock outstanding or issuable upon conversion or exercise of outstanding securities of the Company to exceed the number of Shares then issuable under the Agreement.



Atara Biotherapeutics, Inc.

February 27, 2020

Page 2

Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware. Our opinion is based on these laws as in effect on the date hereof. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold and issued against payment therefor in accordance with the Agreement, the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to the Company's Annual Report on Form 10-K to be filed with the Commission for incorporation by reference into the Registration Statement.

Very truly yours,

Cooley LLP

By: /s/ Carlton Fleming  
Carlton Fleming

**AMENDMENT NO. 4 TO DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT [ \* ]**

This Amendment No. 4 to the Development and Manufacturing Services Agreement (“**Fourth Amendment**”) is made, entered into as of the date of last signature below (the “**Execution Date**”), and effective as of October 1, 2019 (the “**Fourth Amendment Effective Date**”) by and between **ATARA BIOTHERAPEUTICS, INC.**, a Delaware corporation with offices at 611 Gateway Boulevard, Suite 900, South San Francisco, California 94080 (“**Atara**”); and **COGNATE BIOSERVICES INC.**, a Delaware corporation with offices at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118 (“**Manufacturer**”). Each of Atara and Manufacturer are referred to in this Fourth Amendment as a “**Party**” and together, the “**Parties**.” All capitalized terms used, but not otherwise defined herein, shall have the same meaning ascribed to them in the Services Agreement (as defined below).

**BACKGROUND**

**WHEREAS**, the Parties have entered into that certain Development and Manufacturing Services Agreement (the “**Original Services Agreement**”) effective as of August 10, 2015, pursuant to which Atara engaged Manufacturer to perform certain process development and manufacturing services in relation to Atara’s products, as further described in individual work orders entered into thereunder (the “**Services**”, as further defined in the Services Agreement);

**WHEREAS**, the Parties entered into the First Amendment to the Original Services Agreement effective December 21, 2017 (the “**First Amendment**”) to provide for Atara’s [ \* ] certain Services at Manufacturer’s facility;

**WHEREAS**, the Parties entered into the Second Amendment to the Original Services Agreement effective May 4, 2018, and subsequently amended and restated effective November 4, 2018 (collectively, the “**Amended and Restated Second Amendment**”) to further revise certain terms of the Services Agreement;

**WHEREAS**, the Parties entered into the Third Amendment to the Original Services Agreement effective June 28, 2019 (the “**Third Amendment**”) to further revise certain terms of the Services Agreement;

**WHEREAS**, the Original Services Agreement, as amended by the First Amendment, the Amended and Restated Second Amendment, and the Third Amendment are collectively referred to in this Fourth Amendment as the “**Services Agreement**”;

**WHEREAS**, the Parties have agreed to further amend the Services Agreement to revise the [ \* ] of the Services Agreement [ \* ], extend the Term of the Services Agreement, and revise certain other terms of the Services Agreement; and

**WHEREAS**, Section 15.7 of the Services Agreement provides that the Services Agreement may only be modified by a writing signed by authorized representatives of each Party.

**NOW, THEREFORE**, the Parties desire, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, to amend the Services Agreement as set forth in this Fourth Amendment as of the Fourth Amendment Effective Date.

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1. Section 14.1 of the Services Agreement is hereby deleted in its entirety and replaced as follows:

“**14.1 Term.** This Agreement is effective as of the Effective Date and, unless terminated pursuant to this Article 14 or superseded by a CSA, will expire on December 1, 2019. Notwithstanding the termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to any active or in progress Work Orders until such Work Order has been completed, expired or otherwise terminated in accordance with the terms herein.”

2. Section 1 in Exhibit F to the Services Agreement, [ \* ], is hereby deleted in its entirety and replaced as follows:

[ \* ]

3. Notwithstanding anything herein to the contrary, the Parties agree that in lieu of [ \* ] set forth in Section 1 in Exhibit F to the Services Agreement, [ \* ] is as follows: [ \* ].

4. Section 7 in Exhibit F (to Services Agreement), [ \* ], is hereby deleted in its entirety and replaced as follows:

[ \* ]

5. Section 8 in Exhibit F (to Services Agreement), [ \* ], is hereby deleted in its entirety and replaced as follows:

[ \* ]

6. Schedule 2, [ \* ], to the Third Amendment is hereby deleted in its entirety and replaced with Exhibit B attached to this Fourth Amendment.

7. The Parties acknowledge and agree that as of the Fourth Amendment Effective Date, Atara has [ \* ], in accordance with the terms of the Services Agreement prior to the amendment of the Services Agreement by this Fourth Amendment, and notwithstanding anything to the contrary in this Fourth Amendment, on the Fourth Amendment Effective Date, Manufacturer may invoice Atara for [ \* ]. For the avoidance of doubt, the [ \* ]. For clarity, [ \* ] are set forth in Exhibit A to this Fourth Amendment.

8. The Parties acknowledge and agree the [ \* ], as more specifically set forth in Exhibit B.

9. This Fourth Amendment is governed by and interpreted in accordance with the laws of the State of New York, U.S.A., without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Fourth Amendment. Except as specifically amended by this Fourth Amendment, the terms and conditions of the Services Agreement shall remain in full force and effect. This Fourth Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Except to the extent expressly provided herein, the Services Agreement, as amended by this Fourth Amendment, including all appendices, exhibits and schedules to each of the foregoing, together with all Work Orders executed by the Parties, constitute the entire agreement between the Parties relating to the subject matter of the Services Agreement and supersede all previous oral and written communications, including all previous agreements, between the Parties.

**[SIGNATURE PAGE TO FOLLOW]**

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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**EXHIBIT A**

**Schedule 2**

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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**EXHIBIT B**

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

## AMENDMENT NO. 5 TO DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT

This Amendment No. 5 to the Development and Manufacturing Services Agreement (“**Fifth Amendment**”) is made, entered into and effective as of the date of last signature below (the “**Fifth Amendment Effective Date**”) by and between **ATARA BIOTHERAPEUTICS, INC.**, a Delaware corporation with offices at 611 Gateway Boulevard, Suite 900, South San Francisco, California 94080 (“**Atara**”); and **COGNATE BIOSERVICES INC.**, a Delaware corporation with offices at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118 (“**Manufacturer**”). Each of Atara and Manufacturer are referred to in this Fifth Amendment as a “**Party**” and together, the “**Parties**.” All capitalized terms used, but not otherwise defined herein, shall have the same meaning ascribed to them in the Services Agreement (as defined below).

### BACKGROUND

**WHEREAS**, the Parties have entered into that certain Development and Manufacturing Services Agreement (the “**Original Services Agreement**”) effective as of August 10, 2015, pursuant to which Atara engaged Manufacturer to perform certain process development and manufacturing services in relation to Atara’s products, as further described in individual work orders entered into thereunder (the “**Services**”, as further defined in the Services Agreement);

**WHEREAS**, the Parties entered into the First Amendment to the Original Services Agreement effective December 21, 2017 (the “**First Amendment**”) to provide for Atara’s [ \* ] certain Services at Manufacturer’s facility;

**WHEREAS**, the Parties entered into the Second Amendment to the Original Services Agreement effective May 4, 2018, and subsequently amended and restated effective November 4, 2018 (collectively, the “**Amended and Restated Second Amendment**”) to further revise certain terms of the Services Agreement;

**WHEREAS**, the Parties entered into the Third Amendment to the Original Services Agreement effective June 28, 2019 (the “**Third Amendment**”) to further revise certain terms of the Services Agreement;

**WHEREAS**, the Parties entered into the Fourth Amendment to the Original Services Agreement [ \* ] effective October 1, 2019 (the “**Fourth Amendment**”) to further revise certain terms of the Services Agreement;

**WHEREAS**, the Original Services Agreement, as amended by the First Amendment, the Amended and Restated Second Amendment, the Third Amendment, and the Fourth Amendment are collectively referred to in this Fifth Amendment as the “**Services Agreement**”;

**WHEREAS**, the Parties have agreed to further amend the Services Agreement to extend the Term of the Services Agreement and revise certain other terms of the Services Agreement; and

**WHEREAS**, Section 15.7 of the Services Agreement provides that the Services Agreement may only be modified by a writing signed by authorized representatives of each Party.

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**NOW, THEREFORE**, the Parties desire, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, to amend the Services Agreement as set forth in this Fifth Amendment as of the Fifth Amendment Effective Date.

1. Section 14.1 of the Services Agreement is hereby deleted in its entirety and replaced as follows:

**“14.1 Term.** This Agreement is effective as of the Effective Date and, unless terminated pursuant to this Article 14 or superseded by a CSA, will expire on December 31, 2019. Notwithstanding the termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to any active or in progress Work Orders until such Work Order has been completed, expired or otherwise terminated in accordance with the terms herein.”

2. This Fifth Amendment is governed by and interpreted in accordance with the laws of the State of New York, U.S.A., without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Fifth Amendment. Except as specifically amended by this Fifth Amendment, the terms and conditions of the Services Agreement shall remain in full force and effect. This Fifth Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Except to the extent expressly provided herein, the Services Agreement, as amended by this Fifth Amendment, including all appendices, exhibits and schedules to each of the foregoing, together with all Work Orders executed by the Parties, constitute the entire agreement between the Parties relating to the subject matter of the Services Agreement and supersede all previous oral and written communications, including all previous agreements, between the Parties.

**[SIGNATURE PAGE TO FOLLOW]**

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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## COMMERCIAL MANUFACTURING SERVICES AGREEMENT

THIS COMMERCIAL MANUFACTURING SERVICES AGREEMENT is made as of January 1, 2020 (the "Effective Date") by and between **ATARA BIOTHERAPEUTICS, INC.**, a Delaware corporation with an office at 611 Gateway Blvd, Suite 900, South San Francisco, CA 94080 ("Atara") and **COGNATE BIOSERVICES, INC.**, a Delaware corporation, with an office at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118 ("Manufacturer"). Atara and Manufacturer are each individually a "Party" and collectively the "Parties."

### RECITALS:

WHEREAS, Atara and Manufacturer are Parties to that certain Development and Manufacturing Services Agreement dated August 10, 2015, as amended (the "DMSA");

WHEREAS, Atara now desires to engage Manufacturer to perform certain commercial Manufacturing Services (as those terms are defined below), on the terms and conditions set forth below and in the applicable Work Orders; and Manufacturer desires, on the terms and conditions set forth below and in such Work Orders, to perform such Services for Atara.

### AGREEMENT:

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants of the Parties set forth in this Agreement, the Parties hereto agree as follows:

**1. Definitions.** Unless this Agreement expressly provides to the contrary, the following terms, whether used in the singular or plural, have the respective meanings set forth below.

1.1 "Affiliate" means, with respect to either Atara or Manufacturer, any corporation, company, partnership, joint venture and/or firm which controls, is controlled by or is under common control with Atara or Manufacturer, as the case may be. As used in the definition of Affiliate, "control" means (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), and (b) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect more than fifty percent (50%) of the members of the governing body of such non-corporate entity; provided, however, that, as applied to Atara, the terms of clause (b) will apply equally to corporate as well as non-corporate entities.

1.2 "Agreement" means this Commercial Manufacturing Services Agreement, together with all Appendices, Schedules and Exhibits attached hereto and all Work Orders, Quality Agreements and Change Orders signed by the Parties during the term of this Agreement, as amended from time to time by the Parties in accordance with Section 15.7, and all fully signed Work Orders entered into by the Parties.

1.3 "API/Drug Substance" means the active pharmaceutical ingredient or drug substance identified on the applicable Work Order.

1.4 "Applicable Law" means all ordinances, rules, regulations, laws, requirements, guidances and court orders of any kind whatsoever of any competent Authority applicable to the Manufacture, storage, import, export, transport, marketing, promotion, processing, distribution, sale and/or use of the Product, as amended from time to time including all applicable cGMP.

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- 1.5                    “Atara Equipment” means the Equipment, if any, identified on the applicable Work Order as being provided by Atara or purchased or otherwise acquired by Manufacturer at Atara’s expense.
- 1.6                    “Atara Indemnitees” has the meaning set forth in Section 12.1.
- 1.7                    “Atara Materials” means Patient Materials and [ \* ] reagent.
- 1.8                    “Atara-Supplied Raw Materials” means the raw materials supplied by Atara in accordance with Section 4.1.
- 1.9                    “Atara Technology” means (a) Atara Materials and any intermediates, components, or derivatives of Atara Materials; (b) Product and any intermediates, components, or derivatives of Product; (c) Specifications; and (d) the Technology of Atara (i) existing prior to the Effective Date, or (ii) owned, conceived, created, developed or obtained by or on behalf of Atara independent of this Agreement and [ \* ].
- 1.10                  “Authority” means any competent government regulatory authority responsible for granting approvals, licenses, registrations, or authorizations necessary for the performance of Services under this Agreement or for issuing regulations pertaining to the Manufacture, storage, import, export, transport, marketing, promotion, processing, sale, distribution and/or use of Product in the intended country of use, including without limitation, the FDA.
- 1.11                  “Batch” means a specific quantity of Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the applicable Batch record. [ \* ].
- 1.12                  “Batch Documentation” has the meaning set forth in Section 6.2.
- 1.13                  [ \* ]
- 1.14                  “Business Day” means any day except Saturday, Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of Tennessee or California are authorized or required by law or other governmental action to close.
- 1.15                  “Certificate of Analysis” means a document signed by an authorized representative of Manufacturer, describing Specifications for, and testing methods applied to, Product, and the results of testing.
- 1.16                  “Certificate of Compliance” means a document signed by an authorized representative of Manufacturer, certifying that a particular Batch was Manufactured in accordance with cGMP (if applicable), all other Applicable Law, and the Specifications.
- 1.17                  “cGMP” means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by the applicable Authority, as may be amended from time to time, and as are applicable to the Product, including, without limitation: (a) for US cGMP compliance, the current Good Manufacturing Practices regulations set forth in 21 CFR 210, 211, 1271 and (b) for EU cGMP compliance, the EU GMP guidelines Eudralex Volume 4 (2003/94/EC; EC GMP guidelines and relevant annexes), the Advanced Therapy Medicinal Product EU Directive 1394/2007/EC and the EU Tissue and Cells Directives: Parent Directive 2004/23/EC (Donation, Procurement, Testing of Human Tissues and Cells) and the two technical directives, 2006/17/EC and 2006/86/EC, and the PIC/S Guide to Good Manufacturing Practice for Medicinal Products - PE009-13.

- 1.18 “Change Order” has the meaning set forth in Section 5.3(a).
- 1.19 “Confidential Information” has the meaning set forth in Section 10.1.
- 1.20 “Disposition” has the meaning set forth in the Quality Agreement.
- 1.21 “Effective Date” has the meaning set forth in the preamble.
- 1.22 “Equipment” means any equipment or machinery, including Atara Equipment, used by Manufacturer in the performance of Services, including without limitation, the Manufacturing of Product, or the holding, processing, testing or release of Product.
- 1.23 “Facility” means the facilit(ies) of Manufacturer identified in the applicable Work Order.
- 1.24 “FDA” means the United States Food and Drug Administration, and any successor agency having substantially the same functions.
- 1.25 “FDCA” means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 et seq., as amended from time to time.
- 1.26 “*force majeure*” has the meaning set forth in Section 15.2.
- 1.27 “Improvements” means all Technology and discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements, writings or rights (whether or not protectable under patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice in the performance of Services under this Agreement.
- 1.28 “Initial Work Order” means the first Work Order agreed to and executed by the Parties on the Effective Date, and as attached hereto as Appendix A.
- 1.29 [ \* ]
- 1.30 “Manufacture” and “Manufacturing” means the performance of any steps, processes and activities in the Manufacturing Process necessary to produce Product, including the manufacturing, processing, packaging, labeling, quality control testing, stability testing, release, storage or supply of Product.
- 1.31 “Manufacturer Indemnitees” has the meaning set forth in Section 12.2.
- 1.32 “Manufacturer-Supplied Raw Materials” has the meaning set forth in Section 4.1.
- 1.33 “Manufacturer Technology” means the Technology of Manufacturer (a) existing prior to the Effective Date; or (b) owned, conceived, created, developed or obtained by or on behalf of Manufacturer independent of this Agreement and [ \* ].
- 1.34 “Manufacturing Process” means any and all processes and activities (or any step in any process or activity) used by Manufacturer to Manufacture Product, as set forth in Batch Documentation or master Batch Documentation.
- 1.35 “Patient Materials” means all biological materials derived from a patient or a donor.

- 1.36 “Manufacturing Improvements” has the meaning set forth in Section 9.4.
- 1.37 “Permitted Subcontractor” has the meaning set forth in Section 3.3.
- 1.38 “Planned Deviation” means any deviation that is proposed or identified, in each case, by Atara or Manufacturer, and approved by the Parties in writing prior to performance of the applicable Work Order.
- 1.39 “Product” means any API/Drug Substance or drug product comprised of API/Drug Substance in each case as specified in the applicable Work Order, including, if applicable, bulk packaging and/or labeling as provided in such Work Order and manufactured by Manufacturer for Atara pursuant to this Agreement.
- 1.40 “Quality Agreement” has the meaning set forth in Section 2.2.
- 1.41 “Records” has the meaning set forth in Section 5.4(a).
- 1.42 “Release” has the meaning set forth in the Quality Agreement.
- 1.43 “Representative” has the meaning set forth in Section 3.1.
- 1.44 [ \* ]
- 1.45 “Services” means the Manufacturing and/or other services described in a Work Order entered into by the Parties.
- 1.46 “SOP” means the written standard operating procedures and methods of Manufacturer, as the same may be amended, in accordance with the Quality Agreement.
- 1.47 “Specifications” means, with respect to each Batch, at the time Manufacture is initiated, the list of tests, references to any analytical procedures and appropriate acceptance criteria which are numerical limits, ranges or other criteria for tests described in order to establish a set of criteria to which Product at any stage of Manufacture should conform to be considered acceptable for its intended use that are provided by or approved by Atara, as such specifications are amended or supplemented from time to time by Atara in writing.
- 1.48 “Technology” means all methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).
- 1.49 “Termination Effective Date” means the date upon which termination by a Party of either this Agreement, or in the event of termination of the applicable Work Order, such Work Order, is effective.
- 1.50 “Work Order” means a written work order referencing this Agreement, substantially in the form attached hereto as Appendix B, for the performance of Services by Manufacturer under this Agreement.

## 2. **Engagement of Manufacturer.**



2.1 **Services and Work Orders.** From time to time, Atara may wish to engage Manufacturer to perform Services for Atara. Such Services will be set forth in a Work Order. Each Work Order will be appended to this Agreement, will include the material terms for the project, and may include the scope of work, specified Services, Specifications, deliverables, timelines, milestones (if any), quantity, budget, payment schedule and such other details and special arrangements as are agreed to by the Parties with respect to the activities to be performed under such Work Order. No Work Order will be effective unless and until it has been agreed to and signed by authorized representatives of both Parties. Documents relating to the relevant project, including Specifications, proposals, quotations and any other relevant documentation, will only be effective if attached to the applicable Work Order and incorporated in the Work Order by reference. Each fully signed Work Order will be subject to the terms of this Agreement and will be incorporated herein and form part of this Agreement. Manufacturer will perform the Services in consideration of payment therefor by Atara specified in each fully signed Work Order, as amended by any applicable Change Order(s), and in accordance with the terms and conditions of such Work Order and this Agreement. Notwithstanding the foregoing, nothing in this Agreement will obligate either Party to enter into any Work Order under this Agreement beyond the Initial Work Order executed and delivered simultaneously with this Agreement.

2.2 **Quality Agreement.** Concurrently with the execution of this Agreement, the Parties shall also agree upon and enter into a Quality Agreement containing quality assurance provisions for the commercial Manufacture of Product ("Quality Agreement").

2.3 **Conflict Between Documents.** If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and any Work Order, Quality Agreement, purchase order, or other document or form used by the Parties, the terms of this Agreement control and take precedence, except, in the case of the Quality Agreement, with respect to matters specifically directed to Product quality, cGMP and regulatory compliance with respect to the Manufacture of Products (for which the Quality Agreement controls and takes precedence) and in the case of respect to the fees, costs, expenses, payment and other terms of individual Services (for which the applicable Work Order controls and takes precedence). For clarity, if there are terms in one agreement or document, that are not in another agreement or document, such silence does not constitute a conflict, discrepancy or inconsistency.

### 3. **Project Performance.**

3.1 **Representatives.** Each Party will appoint a representative having primary responsibility for day-to-day interactions with the other Party for the Services (each, a "Representative"), who will be identified in the applicable Work Order. Each Party may change its Representative by providing written notice to the other Party in accordance with Section 15.4; provided that each Party will use [ \* ] to provide the other Party with at least [ \* ] prior written notice of any change in its Representative for the Services. Except for notices or communications required or permitted under this Agreement, which will be subject to Section 15.4, or unless otherwise mutually agreed by the Parties in writing, all communications between Manufacturer and Atara regarding the conduct of the Services pursuant to such Work Order will be addressed to or routed directly through the Parties' respective Representatives.

### 3.2 **Communications.**

(a) **Operations Meetings; Production Forecasts.** The Parties will hold plant leadership team meetings via teleconference or in person, on a periodic basis as agreed upon by the Representatives. Notwithstanding the foregoing, the Parties will hold a [ \* ] meeting of the plant leadership team members from each Party which shall be held in person, unless the Parties mutually agree to hold such meeting by teleconference ("Operations Meeting"). In each Operations Meeting, Atara will provide a [ \* ] demand forecast ([ \* ] forecast, the "Demand Forecast") so that Manufacturer can prepare a production

schedule and plan for the purchase of the necessary raw materials and consumables to be provided by Manufacturer under the applicable Work Order. The Demand Forecast will be binding on Atara with respect to (i), subject to the remainder of this Section 3.2(a) and Schedule 1, Section 1 of the Initial Work Order, [ \* ] for production of the [ \* ] such Demand Forecast (the “Committed Materials Costs”), and (ii) subject to Schedule 1, Section 1 of the Initial Work Order, [ \* ]. Atara will also provide to Manufacturer at each Operations Meeting, where reasonably practicable, a [ \* ] demand forecast covering an additional [ \* ] (i.e. so that the total forecast covers a period of [ \* ]). Within [ \* ] of receiving the Demand Forecast, Manufacturer will prepare a draft invoice [ \* ]. Manufacturer will submit this draft invoice [ \* ] to Atara [ \* ], and upon Atara’s approval, Manufacturer will invoice Atara for (A) [ \* ] and (B) the full [ \* ] on all of the Manufacturer-Supplied Raw Materials. Atara will fully satisfy the [ \* ] within [ \* ] following the date of such invoice. Upon receipt of the [ \* ], Manufacturer will place orders for the Manufacturer-Supplied Raw Materials listed in the [ \* ] to the [ \* ] invoice. Notwithstanding anything to the contrary in the Agreement or elsewhere, Manufacturer has no obligation to order or purchase (and will not be responsible for any associated delays related to such order or purchase) any materials to be purchased by Manufacturer pursuant to any Work Order until after Atara has approved the order and fully satisfied the [ \* ]. At the end of each month, Manufacturer will invoice Atara for Manufacturer’s out of pocket cost (including shipping) for Manufacturer-Supplied Raw Materials that Manufacturer received during the applicable [ \* ] plus the [ \* ], less the amount of [ \* ] received from Atara during such month. Subject to Schedule 1, Section 1 of the Initial Work Order, if Atara orders less than [ \* ] [ \* ], then any raw materials and supplies purchased by Manufacturer that have been paid for by Atara as Committed Materials Costs shall be held by Manufacturer and used for Manufacture of [ \* ] ordered by Atara in subsequent periods (and covered by subsequent Demand Forecasts), provided that Manufacturer may, upon prior written notice to Atara, dispose of or destroy any such raw materials that are outside their shelf life, or are otherwise unsuitable for use in Manufacture of subsequent [ \* ], [ \* ] with respect to [ \* ], [ \* ]. The Financial Terms Schedule in the applicable Work Order sets forth the price and payment terms applicable to each of such Batches of Product Manufactured.

**Manufacturer Operations Meeting Reports.** In each Operations Meeting, Manufacturer will provide [ \* ]. Each Party will cover its own expenses with respect to the attendance of all Operations Meetings. [ \* ].

(b) **Production Forecast.** Without limiting Atara’s obligations to provide the Demand Forecast (and the [ \* ] forecast of production) at each Operations Meeting, as set forth in Section 3.2, within [ \* ] following the Effective Date, Atara will provide to Manufacturer a [ \* ] [ \* ] forecast of its estimated production requirements for Product ([ \* ]) for the [ \* ] period [ \* ] the Effective Date, prepared in good faith and on reasonable grounds, and reflecting Atara’s commercially reasonable estimate of its needs for Product over the applicable period.

3.3 **Subcontracting.** Manufacturer may not subcontract with any third party including any Affiliate of Manufacturer, to perform any of its obligations under this Agreement without the prior written consent of Atara (each such subcontractor, a “Permitted Subcontractor”). For clarity, execution of the Work Order constitutes prior written approval that such subcontractors shall be deemed Permitted Subcontractors for purposes of the preceding sentence to the extent such subcontractors are specified in the applicable Work Order. Manufacturer will be [ \* ] Permitted Subcontractor, and [ \* ]. Manufacturer will cause any such Permitted Subcontractor to be bound by, and to comply with, the terms of this Agreement, as applicable, including all confidentiality, quality assurance, regulatory and other obligations and requirements of Manufacturer set forth in this Agreement. In no event will Manufacturer be responsible for the performance of any third party retained by Atara to perform any services in connection with the Services rendered by Manufacturer, including suppliers, distributors, consultants, agents or testing entities, [ \* ].

3.4 **Duty to Notify.** Manufacturer will [ \* ] notify Atara if at any time during the term of this Agreement Manufacturer believes that it will be unable to perform or complete the Services in accordance with the production schedule agreed in any Work Order. Compliance by Manufacturer with this Section 3.4 will not relieve Manufacturer of any other obligation or liability under this Agreement; provided that Manufacturer's failure to provide notice under this Section 3.4 will not relieve Atara of any obligation or liability it has under this Agreement unless Atara is materially prejudiced by such failure to receive notice.

3.5 **Third Party Providers.** Atara will execute agreements with and be responsible for performance by and payment to certain third party providers of services ancillary to the Services rendered by Manufacturer, as more specifically described in a Work Order.

#### **4. Materials and Equipment.**

4.1 **Supply of Materials.** Manufacturer will supply, in accordance with the payment schedule(s) included in the applicable Work Order, and in accordance with the relevant approved raw material specifications, all materials to be used by Manufacturer in the performance of Services under a Work Order (other than Atara Materials and Atara-Supplied Raw Materials) (collectively, the "**Manufacturer-Supplied Raw Materials**"). Without limiting the foregoing, any such materials that the Parties mutually agree (in writing, email being sufficient) require prepayment will be subject to the financial terms set forth in the applicable Work Order. Atara or its designees will provide Manufacturer with those Atara Materials in accordance with the schedule established at the applicable Operations Meeting. Notwithstanding Manufacturer's obligation to procure all Manufacturer-Supplied Raw Materials for the provision of Services and Manufacture of Product, Atara may, [ \* ], procure and deliver to Manufacturer up to [ \* ] of all raw materials used by Manufacturer (other than Atara Materials, of which Atara may supply [ \* ]) in the performance of Services and/or Manufacture of Product. Manufacturer agrees (a) to acknowledge receipt of all Atara-Supplied Raw Materials and Atara Materials received by Manufacturer; (b) not to provide Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials (that have been pre-paid for by Atara) or Atara Materials to any third party without the express prior written consent of Atara; (c) not to use Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials (that have been pre-paid for by Atara) or Atara Materials for any purpose other than conducting the Services, and without limiting the generality of the foregoing, will not analyze, characterize, modify or reverse engineer any Atara Materials or take any action to determine the structure or composition of any Atara Materials unless required pursuant to a signed Work Order (or necessary to confirm that all applicable standards are met, solely in connection with [ \* ]Atara's prior written consent); and (d) to destroy or return to Atara all unused quantities of Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials (that have been pre-paid for by Atara) and Atara Materials according to Atara's written directions and at Atara's sole cost and expense.

4.2 **Ownership of Materials.** Atara will [ \* ] to and [ \* ] the Atara Materials, the Atara-Supplied Raw Materials, Product and any intermediates and components of the Product, the Atara Materials and the Atara-Supplied Raw Materials and any work in process at each and every stage of the Manufacturing Process (other than Manufacturer-Supplied Raw Materials) [ \* ]. All costs of Manufacturer-Supplied Raw Materials incurred by Manufacturer and payable by Atara under this Agreement (including any Work Order) will be sold and invoiced to Atara by Manufacturer and paid by Atara based on [ \* ]. [ \* ], Manufacturer will invoice Atara and Atara will pay Manufacturer for Manufacturer's out of pocket cost [ \* ]. For the avoidance of doubt, the [ \* ] provided for in this Section 4.2 applies to all Manufacturer-Supplied Raw Materials purchases actually made by Manufacturer for resale to Atara. Manufacturer will provide within the Facility an area or areas where the Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, Atara Materials, Product, any intermediates and components of Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, Atara Materials or Product, and any work in process are segregated and stored in accordance with the Specifications and cGMP (if applicable), and in such a way as to be able at all times to clearly distinguish such materials from products and materials belonging

to Manufacturer, or held by it for a third party's account. Atara will provide the Atara-Supplied Raw Materials and Atara Materials (and any intermediates and components of any Atara-Supplied Raw Materials and Atara Materials) to Manufacturer free and clear of all liens and encumbrances and Manufacturer will ensure that such Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, Atara Materials and Product, any intermediates and components of any Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, Atara Materials or Product, and any work in process are free and clear of any liens or encumbrances. Manufacturer will at all times take such [ \* ] measures as are required to protect the Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, Atara Materials, Product, any intermediates and components of any Atara-Supplied Raw Materials, Atara Materials or Product, and any work in process from loss, damage and theft at all stages of the Manufacturing Process. Manufacturer will [ \* ] notify Atara if at any time it believes any Product, Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, or Atara Materials, or any intermediates and components of any Atara Materials, Atara-Supplied Raw Materials, Manufacturer-Supplied Raw Materials, or Product, or any work in process have been damaged, lost or stolen.

4.3 **Transition of Raw Materials and Certain Services Provided for under DMSA.** The Parties acknowledge and agree that upon the termination of the DMSA, except for the raw materials needed to complete the work orders under the DMSA as mutually agreed by the Parties, all other raw materials in Manufacturer's possession and control that are subject to the DMSA or any Work Order thereof that Atara has paid for, [ \* ], shall transfer to this Agreement and be deemed as either "Atara Materials" or "Atara-Supplied Raw Materials," as the case may be. Atara and Manufacturer hereby agree the following work orders issued under the DMSA are terminated as of the Effective Date: (i) [ \* ]; (ii) [ \* ]; and (iii) [ \* ]. The relevant services under such Work Orders are transitioned from the DMSA to this Agreement and included in the Initial Work Order.

4.4 **Supply of Equipment.** Unless otherwise agreed in a Work Order, Manufacturer will supply all Equipment necessary to perform the Services, except that Atara will supply the Atara Equipment, if any. Manufacturer will not use the Atara Equipment except in performance of Services under the applicable Work Order. The Atara Equipment will be delivered to Manufacturer's Facility free and clear of all liens and encumbrances. Title to any such delivered Atara Equipment will remain with Atara and Manufacturer will ensure that the Atara Equipment is properly labeled as Atara property and remains free and clear of any liens or encumbrances. At Atara's written request, the Atara Equipment will be returned to Atara, or to Atara's designee, at Atara's sole cost and expense. Manufacturer will be responsible, at Atara's cost, for maintenance of the Atara Equipment. To the extent Atara provides spare parts for the Atara Equipment, such spare parts will remain the property of Atara and will be used by Manufacturer only for maintenance of the Atara Equipment. Manufacturer will [ \* ] notify Atara if [ \* ] any Atara Equipment has been damaged, lost or stolen.

4.5 **Product and Materials Inventory Reporting and Audit.** During the term of this Agreement, Manufacturer shall provide to Atara, in a mutually agreed format : (i) [ \* ] reports of [ \* ]. Atara will also have the right, at its expense, to conduct [ \* ] audit of the Product and raw material inventory levels per [ \* ] period upon reasonable prior written notice of not less than [ \* ] to Manufacturer, at a mutually agreed time, and Manufacturer agrees to cooperate with Atara in such inventory audit.

5. **Manufacture of Product.**

5.1 **Applicable Law.** Manufacturer will comply with all Applicable Law in performing Services under this Agreement.

5.2 **Facility.**

(a) **Performance of Services.** Manufacturer will perform all Services at the Facility, provide all staff necessary to perform the Services in accordance with the terms of the applicable Work Order and this Agreement, and, except as otherwise set forth in a Work Order, hold at such Facility, all Equipment, Atara Equipment, Atara Materials and other items used in the Services. Manufacturer will not change the location of such Facility or use any additional facility for the performance of Services under this Agreement without [ \* ] prior written notice to, and prior written consent from Atara, which consent will not be unreasonably withheld, conditioned, or delayed (it being understood and agreed that Atara may withhold consent pending satisfactory completion of a quality assurance audit and/or regulatory impact assessment of the new location or additional facility, as the case may be). Manufacturer will maintain, [ \* ], the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of cGMP (if applicable) and all Applicable Law.

(b) **Facility Validation.** Atara will be responsible for performing all validation of any Atara Equipment, unless otherwise agreed in any Work Order. Manufacturer will be responsible for performing all validation of the Facility, Equipment and cleaning and maintenance processes employed in the Manufacturing Process in accordance with cGMP (if applicable), Manufacturer's SOPs, the applicable Quality Agreement (if any), Applicable Law, and in accordance with any other validation procedures established by Atara and agreed to in writing by Manufacturer, and the applicable Work Order.

(c) **Licenses and Permits.** Manufacturer will be responsible for obtaining and maintaining throughout the term of this Agreement, at its expense, any Facility or other licenses or permits, and any regulatory and government approvals necessary for the performance of Services by Manufacturer under this Agreement. At Atara's request, Manufacturer will provide Atara with copies of all such approvals and submissions to Authorities and, subject to the obligations of confidentiality set forth herein and Applicable Law, Atara will have the right to use any and all information contained in such approvals or submissions to the extent required in connection with regulatory approval and/or commercial development of Product.

(d) **Access to Facility.** During the term of this Agreement, Manufacturer will permit Atara or its duly authorized representatives to [ \* ] Services related to and including cGMP Manufacture of Product at the Facility, including the Manufacturing of any Batch of Product; provided, that, Atara will (i) use only common areas and those areas of the Facility where Services are performed and (ii) will not enter or attempt to access any areas indicated by Manufacturer as accessible to authorized personnel only. For clarity, Manufacturer will [ \* ] the performance of such Services. Manufacturer also agrees that Atara and its duly authorized agents will have access, during normal business hours and during active Manufacturing, to inspect those portions of the Facility where the Product is Manufactured and to inspect the Manufacturing Process to [ \* ], including inspection of (i) the Equipment and materials used in the performance of Services; (ii) the holding facilities for such materials and Equipment; and (iii) all Records relating to such Services and the Facility; provided that such access by Atara must not unduly interfere with or impede Manufacturer's normal business operations or timely performance of the Services. Atara will and will cause its duly authorized representatives (including the [ \* ]) to, comply with the Manufacturer's reasonable instructions and/or monitoring policies (as the same may be amended from time to time) at all times any Atara representatives ([ \* ]) and all other representatives or agents of Atara) are in the Facility. Subject to Manufacturer's obligations under Applicable Law and obligations of confidentiality to third parties, Manufacturer's reasonable instructions shall not [ \* ] Atara from [ \* ]; provided, that Atara shall not have access to any cleanroom suite or storage areas in the Facility used or allocated for providing services to other current, prospective or future clients of Manufacturer.

### 5.3 **Changes to Work Orders, Manufacturing Process and Specifications.**

(a) **Changes to Work Orders.** If the scope of work of a Work Order changes, then the applicable Work Order may be amended as provided in this Section 5.3(a). If a required modification to a Work Order is identified by Atara or by Manufacturer, the identifying Party will notify the other Party in writing [ \* ]. Manufacturer will provide Atara with a change order containing a description of the required modifications and their effect on the scope, fees and timelines specified in the Work Order (“Change Order”), and will use [ \* ] to do so within [ \* ] of receiving or providing such notice, as the case may be. No Change Order will be effective unless and until it has been signed by authorized representatives of both Parties. If Atara does not approve such Change Order, and has not terminated the Work Order, but requests the Work Order to be amended to take into account the modification, then the Parties will use reasonable efforts to agree on a Change Order that is mutually acceptable. If practicable, [ \* ]; provided [ \* ] Change Order. Notwithstanding anything to the contrary in the preceding sentence, during such negotiations, (a) Atara is [ \* ] and (b) Manufacturer is [ \* ]. Manufacturer will not commence work in accordance with any such Change Order until it is authorized in writing by Atara and fully signed by the Parties. Atara will be responsible for all mutually agreed upon additional fees, costs and expenses related to any Change Order or continued performance under any existing Work Order, whether the modifications are proposed by Atara or Manufacturer, as set forth in such Change Order.

(b) **Changes to Process/ Specifications.** Any amendment, change or other modification to the Manufacturing Process or Specifications for any Product must be approved in advance by [ \* ] and will be made in accordance with the change control provisions of the applicable Quality Agreement, if any.

#### 5.4 **Record and Sample Retention.**

(a) **Records.** Manufacturer will keep complete and accurate records (including reports, accounts, notes, data, and records of all information and results obtained from performance of Services) of all work done by it under this Agreement, in form and substance as specified in the applicable Work Order, the applicable Quality Agreement, and this Agreement (collectively, the “Records”). All such Records will be the property of Atara. Except as required by or necessary to comply with Applicable Law, enforce its rights or perform its obligations under this Agreement, any Work Order, or the Quality Agreement, Manufacturer will not transfer, deliver or otherwise provide any such Records to any Party other than Atara, without the prior written approval of Atara. All original Records of the performance of Services, including without limitation, the Manufacture of Product under this Agreement will be retained and archived by Manufacturer in accordance with cGMP (if applicable) and Applicable Law, but in no case for less than a period of [ \* ] following completion of the applicable Work Order. Such archived Records will be available at reasonable, mutually agreed times, during normal business hours, for inspection, examination and copying by or on behalf of Atara, [ \* ]. For the sake of clarity, costs and expenses in connection with Atara’s review of Records [ \* ] in connection with the Release of a Batch or Disposition is included in the Batch Fees. Upon Atara’s request and [ \* ], Manufacturer will [ \* ] provide Atara with hard copies of such Records following written request therefor. Atara will be provided electronic access to completed Records [ \* ]. [ \* ] after completion of a Work Order, all of the aforementioned records will be sent to Atara or Atara’s designee at Atara’s sole cost and expense; provided, however, that [ \* ] such Records retained in Manufacturer’s archives for an additional period of time at a [ \* ] charge to Atara. Manufacturer will retain copies of all of such Records and Atara will provide Manufacturer full access to all original Records if Manufacturer is required or compelled to furnish any of such original Records in connection with a regulatory inspection by any Authority or otherwise in connection with Applicable Law.

(b) **Sample Retention.** Manufacturer will take and retain, for such period and in such quantities as may be required by cGMP (if applicable) and the applicable Quality Agreement, samples of Product from the Manufacturing Process produced under this Agreement. Further, upon Atara’s written request, Manufacturer will submit such samples to Atara at [ \* ].

5.5 **Regulatory Matters.**

(a) **Regulatory Approvals.** Atara will be responsible for obtaining, at its sole cost and expense, all regulatory and governmental approvals and permits necessary for Atara's use, sale, marketing, promotion, advertising, vending, trading, offering, or commercializing, as applicable, of any Product Manufactured under this Agreement, including investigational new drug application, biologics license application, new drug application, and abbreviated new drug application submissions and any analogous submissions filed with the appropriate Authority of a country other than the United States ("Atara Approvals"). Manufacturer shall provide Atara with all supporting data and information relating to the Manufacture of Product necessary for obtaining such approvals, including all Records, raw data, reports, authorizations, certificates, methodologies, Batch Documentation, raw material specifications, SOPs or references to a drug master file or international equivalent, as the case may be, standard test methods, Certificates of Analysis, Certificates of Compliance and other documentation, in each case, in the possession or under the control of Manufacturer and applicable to the [ \* ] within [ \* ] of Atara's written request (email being sufficient).

5.6 **Waste Disposal.** The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated in connection with the Services will be the responsibility of Manufacturer [ \* ].

5.7 **Safety Procedures.** Manufacturer will be solely responsible for implementing and maintaining health and safety procedures for the performance of Services and for the handling of any materials or hazardous waste used in or generated by the Services. Manufacturer, in consultation with Atara, will develop safety and handling procedures for API/Drug Substance and Product; provided, however, that Atara [ \* ].

6. **Testing and Acceptance Process.**

6.1 **Testing by Manufacturer.** The Product Manufactured under this Agreement will be Manufactured in accordance with the Manufacturing Process approved by Atara, and with cGMP (unless otherwise expressly stated in the applicable Work Order). Each Batch of Product will be sampled and tested by Manufacturer, a Permitted Subcontractor, Atara, or by a third party retained by Atara, against the Specifications, and the quality assurance department of Manufacturer will review the documentation relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with cGMP (if applicable) and the Manufacturing Process.

6.2 **Provision of Records.** If, based upon such tests and documentation review, a Batch of Product conforms to the Specifications and was Manufactured according to cGMP (if applicable) and the Manufacturing Process, then a [ \* ] will be completed and approved by the quality assurance department of Manufacturer. [ \* ] (collectively, the "[ \* ]") [ \* ]. If Atara requires additional [ \* ], these will be provided by Manufacturer to Atara at [ \* ].

6.3 **Review of Batch Documentation.** Each Party will review the Batch Documentation for each Batch of Product and may test samples of the Batch of Product per the applicable Work Order against the Specifications. Atara will notify Manufacturer in writing of its acceptance or rejection of such Batch based on not more than [ \* ] review cycles completed within a period of [ \* ] commencing upon Atara's receipt of the Batch Documentation relating to such Batch. Each Party will use [ \* ] to review the Batch Documentation within less than [ \* ] review cycles and within less than [ \* ] following receipt. During this

review period, the Parties agree to respond promptly, but in any event within [ \* ], to any reasonable inquiry or request for a correction or change by the other Party with respect to such Batch Documentation.

6.4 [ \* ]

6.5 [ \* ]; **Disputes.**

(a) Upon Atara's receipt and review of the Batch Documentation within the time period set forth in Section 6.3, Atara shall in accordance with Section 6.3 notify Manufacturer in writing if Atara believes, in good faith and based on reasonable grounds that any Batch (i) [ \* ] shall be addressed in accordance with the remainder of this Section 6.5 and Section 6.6.

(b) If a Batch is a [ \* ], then a root cause analysis on such [ \* ] will be undertaken in accordance with subsection (c) below ([ \* ]). Atara will be required to pay for [ \* ] of the amount set forth in invoices for Product that is a [ \* ] within the time frame required under the applicable Work Order, with the remainder of such invoiced amount held pending the determination of an Investigational Process. Payment of an invoice by Atara will not constitute a waiver of remedies available to Atara under Section 6.6, except for claims that a Batch is or was a [ \* ] where Product in such Batch is or was approved for Final Disposition (as defined in in the applicable Work Order).

(c) [ \* ]

(d) [ \* ] analysis set forth in subsection (c) above:

(i) [ \* ].

(ii) [ \* ].

(e) If a [ \* ] is finally determined pursuant to this Section 6.5 ([ \* ], as applicable) to be (i) a [ \* ], then Section 6.6(a) shall apply or (ii) an [ \* ], then Section 6.6(b) shall apply.

(f) In addition to [ \* ] and will decide [ \* ], or to terminate [ \* ].

(g) [ \* ].

6.6 **Product Non-Compliance and Remedies.**

(a) If the Parties agree or if determined in accordance with Section 6.5 above that a Batch of Product is a [ \* ] then, Manufacturer will, [ \* ]:

(i) [ \* ]; or

(ii) [ \* ].

(b) If the Parties agree or if determined in accordance with Section 6.5 above that a Batch of Product is an Atara Non-Conforming Batch, then Atara will [ \* ], and shall pay all amounts owed with respect to such Atara Non-Conforming Batch within [ \* ] following delivery of an invoice by Manufacturer after completion of the [ \* ]. Atara will pay Manufacturer the fees, costs and expenses for such [ \* ] in accordance with the applicable Work Order, and Atara will not be entitled to the remedies set forth in Section 6.6(a).



(c) For clarity, unless the [ \* ] is determined to be a [ \* ] pursuant to Section 6.5, and without limiting [ \* ], Manufacturer will not be responsible for [ \* ] under clause (a)(i) of this Section 6.6 or for [ \* ] under clause (a)(ii) of this Section 6.6.

6.7 **Disposition of Non-Conforming Product.** The ultimate disposition of non-conforming Product will be the responsibility of Atara's quality assurance department.

6.8 **Product Recalls.**

(a) **Recalls.** In the event: (i) any Authority or other national government authority issues a request, directive or order that the Product (or any recall of a final product that incorporates a Product); (ii) a court of competent jurisdiction orders such a recall, or (iii) Atara reasonably determines, after giving due consideration, in good faith, to Manufacturer's comments regarding any such recall, that Product (or any recall of a final product that incorporates a Product) should be recalled, the Parties shall take all appropriate corrective actions, and shall cooperate in any governmental investigations surrounding the recall.

(b) **Product [ \* ]; Expenses.** In the event that such recall results from: (i) from [ \* ], or (ii) in whole or in part from [ \* ] cGMP or the Manufacturing Process, Manufacturer shall [ \* ] Products that were recalled [ \* ]. Manufacturer shall use [ \* ] such Product [ \* ]. [ \* ]. In the event that the recall does not result from: (i) from [ \* ], or (ii) in whole or in part [ \* ] with cGMP or the Manufacturing Process, [ \* ]. For purposes of this Section 6.8(b), "[ \* ]" of a recall shall include [ \* ].

7. **Shipping and Delivery.**

7.1 **Shipping and Delivery.** Manufacturer agrees not to ship Product to Atara or its designee until it has received a written approval from Atara or Atara's designee to Release such Product and tender it to Atara's carrier. Manufacturer will follow the instructions for shipping and packaging agreed to by the Parties in the applicable Work Order, or as otherwise agreed to by the Parties in writing. Delivery terms will be [ \* ] ([ \* ]) Manufacturer's Facility to an agent of the Atara-designated carrier on such dates as are agreed by the Parties ("Delivery"). A bill of lading will be furnished to Atara with respect to each shipment.

7.2 **Product Returns.** If Atara requests Manufacturer accept return of Product previously Delivered or of samples, raw materials, media, reagents or any such Product, samples, raw materials, media or reagents (each, a "Return"), Atara must provide to Manufacturer written documentation evidencing a fully maintained chain of custody from Delivery of Product through Return to an authorized representative of Manufacturer at the Facility. Such written documentation must [ \* ]. Manufacturer will not re-Deliver Returned Product (or other materials) without prior express written authorization from, and agreement by, Atara [ \* ].

8. **Fees and Payments.**

8.1 **Price.** The price of Product and/or the fees and expenses for the performance of Services will be set forth in the applicable Work Order. All dollar (\$) amounts specified in this Agreement are United States dollar amounts and all payments to be made under this Agreement will be made in United States dollars.

8.2 **Invoice.** Performance of the Services by Manufacturer is dependent upon Atara's full satisfaction of all [ \* ] amounts payable by Atara to Manufacturer under this Agreement in accordance with

the applicable payment terms under this Agreement or the applicable Work Order. Manufacturer will invoice Atara according to the invoice schedule in the applicable Work Order, referencing in each such invoice the Work Order(s) to which such invoice relates. Unless otherwise specified in the applicable Work Order, payment of [ \* ] amounts ([ \* ]) will be due [ \* ] after Atara's receipt of electronic transmission of the invoice (and reasonable supporting documentation pertaining to any disbursements). Payments will be made in United States Dollars. A [ \* ] service charge will be applied to all [ \* ] overdue balances ([ \* ]).

8.3 **Payments.** Atara will make all payments pursuant to this Agreement by wire transfer in immediately available funds to a bank account designated in writing by Manufacturer in the invoice associated with the applicable Work Order.

8.4 **Financial Records.** Manufacturer will keep accurate records of all Services performed and invoice calculations, and, upon the request of Atara, will permit Atara or its duly authorized agents to examine such records during normal business hours and in accordance with the terms of Section 5.2(d) for the purpose of verifying the correctness of all such calculations.

8.5 **Taxes.** All duty, sales, use or excise taxes imposed by any governmental entity that apply to the provision of Services will be borne solely by Atara (other than taxes based upon the income of Manufacturer).

8.6 [ \* ]

8.7 [ \* ].

## 9. **Intellectual Property Rights.**

9.1 **Atara Technology.** All rights to and interests in Atara Technology will remain solely in Atara and no right or interest therein is transferred or granted to Manufacturer under this Agreement. Manufacturer acknowledges and agrees that it does not acquire a license or any other right to Atara Technology except for the limited purpose of carrying out its duties and obligations under this Agreement and that such limited, non-exclusive, license will expire upon the completion of such duties and obligations or the termination or expiration of this Agreement, whichever is the first to occur.

9.2 **Manufacturer Technology.** All rights to and interests in Manufacturer Technology will remain solely in Manufacturer and, except for the limited, non-exclusive license set forth in this Agreement, no right or interest therein is transferred or granted to Atara under this Agreement. Manufacturer hereby grants to Atara a [ \* ], license to Atara, [ \* ] to the extent [ \* ]. Manufacturer covenants and agrees that in the event Manufacturer Technology is used in the Manufacture of Product under this Agreement that is [ \* ], Manufacturer hereby grants to Atara a [ \* ], license to Atara [ \* ] to [ \* ] such Manufacturer Technology to the extent [ \* ].

9.3 **Improvements.** Manufacturer agrees (a) to promptly disclose [ \* ]Improvements; (b) that [ \* ] Improvements will be the sole and exclusive property of Atara; and (c) that Manufacturer will assign and does assign [ \* ]Improvements to Atara (or its designee) [ \* ]. Manufacturer will take such steps as Atara may reasonably request (at Atara's sole cost and expense) to vest in Atara (or its designee) ownership of [ \* ] Improvements.

9.4 **Non-Exclusive License.** Atara hereby grants to Manufacturer a non-exclusive, perpetual, irrevocable, fully paid-up, worldwide license, with the right to sub-license, to [ \* ] Improvements made in the performance of the Services that [ \* ] or that are [ \* ](a) [ \* ] or (b) [ \* ](collectively, "Manufacturing Improvements").

9.5 **Patent Filings.** Atara will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any patents that claim or cover the Improvements.

9.6 [ \* ].

9.7 **No Express or Implied Licenses.** Except to the extent expressly set forth in this Article 9, neither Party will acquire any right, title or interest (express or implied) in any intellectual property belonging or licensed by a third party to the other Party and no right or license, whether express or implied (by implication, estoppel or otherwise), is granted to one Party by the other, except to the extent expressly authorized by this Agreement

## 10. **Confidentiality.**

10.1 **Definition.** “**Confidential Information**” means any and all non-public scientific, technical, financial regulatory or business information, or data or trade secrets in whatever form (written, oral or visual) that is furnished or made available by one Party (the “**Discloser**”) to the other (the “**Recipient**”) or developed by either Party under this Agreement. Confidential Information of Atara includes (x) Atara Materials, Atara Technology and Improvements; (y) development and marketing plans, regulatory and business strategies, financial information, and forecasts of Atara; and (z) all information of third parties that Atara has an obligation to keep confidential. Confidential Information of Manufacturer includes (w) this Agreement, (x) Manufacturer Technology; (y) development and marketing plans, regulatory and business strategies, financial information, and forecasts of Manufacturer; and (z) all information of third parties that Manufacturer has an obligation to keep confidential.

10.2 **Confidentiality Obligations.** Recipient agrees to (a) hold in confidence all Discloser’s Confidential Information, and not disclose Discloser’s Confidential Information except as expressly provided in Sections 5.5(a) and/or 10.3, without the prior written consent of Discloser; (b) use Discloser’s Confidential Information solely as permitted under this Agreement to carry out Recipient’s obligations under this Agreement (c) treat Discloser’s Confidential Information with the same degree of care Recipient uses to protect Recipient’s own confidential information but in no event with less than a reasonable degree of care; and (d) reproduce Discloser’s Confidential Information solely to the extent necessary to carry out Recipient’s obligations or as permitted under this Agreement (and any agreements executed pursuant to this Agreement), with all such reproductions being considered Discloser’s Confidential Information.

10.3 **Permitted Disclosure.** Recipient may provide Discloser’s relevant Confidential Information to its [ \* ] and [ \* ] agents or representatives of Atara who access the Facility or have access to Manufacturer Confidential Information pursuant to Section 5.2(d), [ \* ]; provided, however, that in each case (a) each of such [ \* ] and all other agents or representatives of Atara who access the Facility or have access to Manufacturer Confidential Information pursuant to Section 5.2(d)), have a bona fide need to know Discloser’s Confidential Information to perform its obligations under this Agreement (including any Work Order executed hereunder), (b) are bound by written obligations of confidentiality with respect to the Discloser’s Confidential Information that are at least as restrictive as those set forth in this Agreement; and (c) Recipient remains liable for the compliance by and breach of such [ \* ] (including, with respect to Atara, [ \* ] and all other agents or representatives of Atara who access the Facility or have access to Manufacturer Confidential Information pursuant to Section 5.2(d)), [ \* ] with such obligations. Recipient may also disclose Discloser’s Confidential Information to third parties only to the extent such disclosure is required to comply with Applicable Law, the rules of any stock exchange or listing entity, or to defend or prosecute litigation; provided, that to the extent not prohibited by Applicable Law, Recipient provides prior written notice of such disclosure to Discloser, takes all reasonable and lawful actions to avoid or minimize the

degree of such disclosure, and cooperates reasonably with Discloser, at Discloser's cost and expense, in any efforts to seek a protective order. If disclosure of Discloser's Confidential Information is nevertheless required, Recipient will disclose only that portion of Discloser's Confidential Information that is legally required and then only to those parties legally required. Furthermore, (i) Atara may disclose Confidential Information of Manufacturer [ \* ] to the Manufacture of Product to [ \* ], and who in each case have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restrictions on use; provided such Confidential Information of Manufacturer shall not include or reference any of the information specified on Appendix E hereto; and (ii) Manufacturer may disclose the [ \* ] of this Agreement and the fact that Manufacturer is performing the Services for Atara to [ \* ], and who in each case have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restrictions on use.

10.4 **Exceptions.** Recipient's obligations of non-disclosure, non-use and confidentiality under this Agreement will not apply to any portion of Discloser's Confidential Information that Recipient can demonstrate, by competent proof:

(a) [ \* ] is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of Recipient or its [ \* ];

(b) [ \* ] is in Recipient's or its [ \* ] possession at the time of disclosure other than as a result of Recipient's or its [ \* ] breach of any legal obligation, as demonstrated by competent and contemporaneous written documentation;

(c) [ \* ] becomes known to Recipient or its [ \* ] on a non-confidential basis through disclosure by sources other than the Discloser having the legal right to disclose such Confidential Information; or

(d) [ \* ] is independently developed by Recipient or its [ \* ] without reference to or reliance upon Discloser's Confidential Information, as demonstrated by competent and contemporaneous written documentation.

10.5 **Injunctive Relief.** Recipient agrees that monetary damages would not be a sufficient remedy for any threatened or actual breach by Recipient or its [ \* ], of the obligations of confidentiality and limitations on use of Confidential Information in this Article 10 and that Discloser, without posting any bond and without liability should relief be denied, modified or vacated, is entitled to equitable relief including an injunction to stop any actual breach. Discloser is entitled to pursue all available remedies, at law or in equity, alternatively or cumulatively, in the event of a threatened or actual breach of this Article 10.

10.6 (a) For a period of [ \* ], (i) Manufacturer will not and will cause its [ \* ] not to, directly or indirectly, hire, engage, employ or solicit for employment (as an employee, consultant or otherwise) any employees or consultants of Atara ("Atara Employees") or induce or attempt to induce any Atara Employees to leave his or her employment or engagement with Atara, or in any way intentionally interfere with the employment relationship between any Atara Employees and Atara, in each case for the purpose of employing or engaging the services of any such Atara Employee or for soliciting any such Atara Employee to become an employee or consultant of Manufacturer or its Affiliates or any other party; provided, however, that nothing herein shall preclude Manufacturer from employing or soliciting any Atara Employee (A) who independently responds to any public advertisement or general solicitation (such as a newspaper advertisement, recruiter solicitation or internet posting) not specifically targeting such Atara Employee or (B) following the termination of such Atara Employee's employment with Atara for any reason, provided, that Manufacturer has not induced such Atara Employee to terminate his or her employment in breach of

Manufacturer's obligations hereunder and (ii) Atara will not and will cause its [ \* ] not to, directly or indirectly, hire, engage, employ or solicit for employment (as an employee, consultant or otherwise) any employees or consultants of Manufacturer ("Manufacturer Employees") or induce or attempt to induce any Manufacturer Employees to leave his or her employment or engagement with Manufacturer, or in any way intentionally interfere with the employment relationship between any Manufacturer Employees and Manufacturer, in each case for the purpose of employing or engaging the services of any such Manufacturer Employee or for soliciting any such Manufacturer Employee to become an employee or consultant of Atara or its Affiliates or any other party; provided, however, that nothing herein shall preclude Atara from employing or soliciting any Manufacturer Employee (A) who independently responds to any public advertisement or general solicitation (such as a newspaper advertisement, recruiter solicitation or internet posting) not specifically targeting such Manufacturer Employee or (B) following the termination of such Manufacturer Employee's employment with Manufacturer for any reason, provided, that Atara has not induced such Manufacturer Employee to terminate his or her employment in breach of Atara's obligations hereunder.

**11. Representations and Warranties.**

**11.1 Manufacturer Representations and Warranties.** Manufacturer represents and warrants to Atara that:

(a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other parties, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by Manufacturer has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Manufacturer, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) the Services will be performed, in all material respects, with requisite care, skill and diligence, by individuals who are appropriately trained and qualified; and in accordance with Applicable Law and industry standards and all applicable provisions of Atara's written policies and procedures that have been provided to Manufacturer and set forth in the applicable Work Order;

(d) the use of the Manufacturer Technology does not violate any patent, trade secret or other proprietary or intellectual property rights of any third party and it will notify Atara in writing should it become aware of any claims asserting such violation;

(e) to the best of Manufacturer's knowledge, the performance of the Services will not violate any patent, trade secret or other proprietary or intellectual property rights of any third party and it will notify Atara in writing should it become aware of any claims asserting such violation. For clarity, the Manufacturer makes no representations or warranties about the intellectual property status of any Atara Technology or its use in connection with the Services;

(f) at the time it is delivered to Atara pursuant to the third sentence of Article 7, the Product Manufactured under this Agreement will (i) have been Manufactured in accordance with cGMP (if applicable) and all other Applicable Law, and subject to Planned Deviations and/or any Change Orders, the Manufacturing Process, the applicable Quality Agreement (if any), and Specifications; and

(g) Manufacturer, its approved subcontractors, and each of their respective officers and directors, as applicable, and any person used by Manufacturer or its approved subcontractors to perform

Services under this Agreement: (a) have not been debarred and are not subject to a pending debarment pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (b) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(0)); (c) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (d) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. Manufacturer will notify Atara [ \* ] if Manufacturer, its approved subcontractors, or any person used to perform Services under this Agreement, or any of their respective officers or directors, as applicable, is, to the best of Manufacturer's knowledge, subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to Manufacturer's knowledge, is threatened.

11.2 **Atara Representations and Warranties.** Atara represents and warrants to Manufacturer that:

(a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other parties, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by Atara has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Atara, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) to the best of Atara's knowledge, none of (i) the Atara Materials, (ii) any intermediates, components, or derivatives of Atara Materials, (iii) Product or any intermediates, components or derivatives of Product, (iv) Specifications, (v) the Atara Technology or (vi) any intellectual property rights in any of (i) through (v), used in the Services infringes or infringe any proprietary or intellectual property rights of any third party; and Atara will notify Manufacturer in writing should it become aware of any claims asserting such violation;

(d) it will not use, sell, market, promote, advertise, vend, trade, offer, or commercialize Product into any regulatory jurisdiction unless and until it receives the necessary (i) Product approvals from the applicable Authority or (ii) express written permission from the applicable Authority prior to receipt of Product approvals.

11.3 **Disclaimer of Other Representations and Warranties.** EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 11 NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

## 12. **Indemnification.**

12.1 **Indemnification by Manufacturer.** Manufacturer will indemnify, defend and hold harmless Atara, its [ \* ] (collectively, the "Atara Indemnitees") against any and all losses, damages, liabilities or expenses (including reasonable attorneys' fees and other costs of defense) (collectively, "Losses") in connection with any and all actions, suits, claims or demands (collectively, "Claims") that may be brought or instituted against any Atara Indemnitee by any third party to the extent they arise out of or relate to any (a) [ \* ]; or (b) [ \* ], except in the case of (a) or (b), to the extent any of such Claims arise out of or relate to (i) [ \* ], (ii) [ \* ] or (iii) [ \* ].

12.2 **Indemnification by Atara.** Atara will indemnify, defend and hold harmless Manufacturer, [ \* ] (collectively, the “Manufacturer Indemnitees”) against any and all Losses in connection with any and all Claims that may be brought or instituted against any Manufacturer Indemnatee by any third party to the extent they arise out of or relate to (a) [ \* ]; (b) [ \* ]; or [ \* ]; or (d) [ \* ].

12.3 **Indemnification Procedures; Calculation of Losses.** Each Party must notify the other Party within [ \* ] of receipt of any claims made for which the other Party might be liable under Section 12.1 or 12.2, as the case may be. Subject to Section 12.4, the indemnifying Party will have the sole right to defend, negotiate, and settle such Claims. The indemnified Party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense; provided, however, that the indemnifying Party will have final decision-making authority regarding all aspects of the defense of any Claim, so long as the indemnifying Party is solely responsible for fully indemnifying the indemnified Party and the indemnified Party is fully and finally released from any liability in respect of such Claim. The Party seeking indemnification will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party.

12.4 **Mitigation.** Each indemnified Party shall take all reasonable steps to mitigate Losses for which indemnification may be claimed by them pursuant to this Agreement upon and after becoming aware of any event that could reasonably be expected to give rise to any such Losses.

12.5 **No Duplicate Recovery Between Parties.** Any liability for indemnification under this Article 12 shall be determined without duplication of recovery by reason of the state of facts giving rise to such liability.

12.6 **Settlement.** Neither Party will be responsible or bound by any settlement of any claim or suit made without its prior written consent; provided, however, that the indemnified Party will not unreasonably withhold, condition, or delay such consent. If a settlement contains an absolute waiver of liability for the indemnified Party, and each Party has acted in compliance with the requirements of this Article 12, then the indemnified Party’s consent will be deemed given. If requested by the indemnifying Party, the indemnified Party will cooperate with the indemnifying Party and its counsel in contesting any Claim or, if appropriate and related to the Claim in question, in making any counterclaim against the third party claimant, or any cross complaint against any other Party (other than the indemnified Party or its Affiliates); provided that the indemnifying Party shall reimburse the indemnified Party for its reasonable out-of-pocket expenses.

12.7 **Limitation of Liability.** NEITHER PARTY WILL BE LIABLE UNDER ANY LEGAL THEORY (WHETHER TORT, CONTRACT OR OTHERWISE) FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, HOWEVER CAUSED, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, [ \* ] NOTHING IN THIS SECTION 12.7 IS INTENDED TO (A) LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY OR (B) APPLY TO AMOUNTS PAYABLE TO MANUFACTURER BY ATARA UNDER THIS AGREEMENT, INCLUDING UNDER ANY WORK ORDER OR UNDER ARTICLE 14. ATARA’S MAXIMUM AGGREGATE LIABILITY WITH RESPECT TO USE OF ANY SERVICE WILL NOT EXCEED [ \* ] AND THE MANUFACTURER’S MAXIMUM AGGREGATE LIABILITY WITH RESPECT TO THE PROVISION OF ALL SERVICES UNDER OR IN CONNECTION WITH THIS AGREEMENT WILL NOT EXCEED [ \* ].

**13. Insurance.**

13.1 **Manufacturer Insurance.** Manufacturer will secure and maintain in full force and effect throughout the term of this Agreement (and for [ \* ] thereafter for claims made coverage), the following minimum insurance coverage with financially sound and nationally reputable insurers with a minimum A. M. Best Rating of [ \* ]:

(a) *Workers' Compensation*, including coverage for occupational disease, with benefits determined by statute, including Employers' Liability of [ \* ];

(b) *Commercial General Liability and Personal/Advertising Injury*, including coverage for contractual liability assumed by Manufacturer and coverage for Manufacturer's independent contractor(s), with at least [ \* ] combined single limit for bodily injury and property damage per occurrence, and a general aggregate limit of [ \* ];

(c) *Products Liability*, exclusive of the coverage provided by the Commercial General Liability policy, with [ \* ] per occurrence and an aggregate limit of at least [ \* ];

(d) *Business Automobile Liability and including non-owned and hired auto liability* with [ \* ] per accident;

(e) *Commercial General Liability, Employers' Liability and Business Automobile Liability* limits may be met with any combination of primary and excess or Umbrella Liability Insurance policy limits to provide [ \* ] per occurrence, and a general aggregate limit of [ \* ];

(f) *"Special Form" Property*, valued at replacement cost, covering loss or damage to the Facility and Atara's property and materials in the care, custody, and control of Manufacturer whether at the Facility, or otherwise with Atara named as loss payee for Atara's property and materials; and

(g) *Crime Insurance* with [ \* ] per occurrence including Employee Dishonesty.

13.2 **Atara Insurance.** Atara will secure and maintain in full force and effect throughout the term of this Agreement (and for [ \* ] thereafter for claims made coverage), [ \* ], (a) prior to any BLA approval (or comparable Authority approval in any other jurisdiction), a similarly situated bio-pharmaceutical company of comparable size and resources, and (b) following any BLA approval (or comparable Authority approval in any other jurisdiction), [ \* ].

13.3 **General.** Liability policies written on a claims-made basis will have a retroactive date no later than the Effective Date of this Agreement. [ \* ]

13.4 **Evidence of Insurance.** Each Party will, upon the execution of this Agreement, after each renewal or material change in coverage, and at any time upon request by the other Party, promptly provide the other Party with a Certificate of Insurance evidencing coverage required under this Section 13, [ \* ], and providing that [ \* ] advance written notice will be given to the other Party of any material change or [ \* ] cancellation in coverage or limits. Upon request, each Party agrees to provide the other Party copies of required insurance policies. The insurance policies set forth in Section 13.2 will cover, among other things, all Atara representatives acting as [ \* ] or whom are otherwise visitors to the Facility. Atara will maintain insurance comparable to the insurance maintained by Manufacturer under Section 13.1(a) and 13.1(b) covering all Atara Employees (as defined in Section 10.6), [ \* ] and all other Atara representatives and agents as visitors to the Facility, in addition to maintaining all other types of insurance required to permit Atara's compliance with Section 13.2. Manufacturer agrees to require Permitted Subcontractors



performing Services to maintain, other types of insurance and/or additional amounts of insurance as is reasonable within the industry for service providers providing comparable services.

13.5 **Insurance Information.** Manufacturer will comply, at Atara's expense, with reasonable requests for information made by Atara's insurance provider representative(s), including permitting such representative(s) to inspect the Facility during operational hours and upon reasonable notice to Manufacturer. In regard to such inspections, the representative(s) will adhere to such guidelines and policies, including those pertaining to safety and non-disclosure as Manufacturer may reasonably require.

**14. Term and Termination.**

14.1 **Term.** This Agreement will take effect as of the Effective Date and, unless earlier terminated pursuant to this Article 14, will expire on [ \* ]. Subject to Manufacturer's agreement thereto in writing, Atara may extend the expiration date of this Agreement to [ \* ] upon written notice to Manufacturer by [ \* ]. Notwithstanding the termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to any active or in progress Work Orders until each such Work Order has been completed, expired or otherwise terminated in accordance with the terms herein or therein.

14.2 **Termination by Atara; Termination by Manufacturer**

(a) Atara will have the right, in its sole discretion, to terminate this Agreement or any Work Order (i) upon [ \* ] prior written notice to Manufacturer; (in which case the Termination Effective Date will be the end of such [ \* ] period unless otherwise agreed by the Parties in writing) and (ii) [ \* ] written notice if (y) Manufacturer is or will be unable to perform the Services in accordance with the terms set forth in the applicable Work Order (as may be amended pursuant to Section 5.3(a)); or (z) Manufacturer fails to obtain or maintain any material governmental licenses or approvals required in connection with the Services that in Atara's reasonable, good faith judgment would have a material adverse impact on the Services.

(b) In addition to and without limiting Manufacturer's rights under Section 8.1, Manufacturer will have the right, by written notice to Atara, at any time, when Atara fails to cure breach of any [ \* ] payment obligation within [ \* ] after receipt of notice by Atara in accordance with Section 15.4 (in which case the Termination Effective Date will be the end of the [ \* ] period after Manufacturer delivered such notice of termination unless otherwise agreed by the Parties in writing); provided that if Atara fails [ \* ] to timely pay [ \* ] invoices in accordance with Section 8.1, Manufacturer may terminate this Agreement or any Work Order if Atara fails to cure such [ \* ] payment breach within [ \* ] of Atara's receipt of notice of payment default in which case the Termination Effective Date will be the expiration of such [ \* ] period. Any Atara dispute with respect to any invoiced amount must be disputed in good faith and with reasonable justification.

14.3 **Termination by Either Party.** Either Party will have the right to terminate this Agreement or any signed Work Orders that are pending by written notice to the other Party, upon the occurrence of any of the following:

(a) the other Party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency law (which proceedings remain undismissed for [ \* ] );

(b) the other Party fails to start and diligently pursue the cure of a material breach of this Agreement (other than breach of any payment obligation by Atara which is governed by Section 14.2(b)) within [ \* ] after receiving written notice from the other Party of such breach; or

(c) a *force majeure* event that will, or continues to, prevent performance (in whole or substantial part) of this Agreement or any pending Work Order for a period of at least [ \* ]. In the case of a *force majeure* event relating solely to a pending Work Order, the right to terminate will be limited to such Work Order.

14.4 **Effect of Termination.** Manufacturer will, upon receipt of a termination notice from Atara under Section 14.2 or Section 14.3, promptly cease performance of the applicable Services and will [ \* ]. In particular, Manufacturer will use its [ \* ] to:

- (a) [ \* ] cancel, to the greatest extent possible, any third party obligations;
- (b) [ \* ] inform Atara of any irrevocable commitments made in connection with any pending Work Order(s) prior to termination;
- (c) [ \* ] return to the vendor for a refund all unused, unopened materials in Manufacturer's possession that are related to any pending Work Order; provided, that Atara will have the option, but not the obligation, to take possession of any such materials;
- (d) [ \* ] inform Atara of the cost of any remaining unused, unreturnable materials ordered pursuant to any pending Work Order(s), and either deliver such materials to Atara (or its designee) or properly dispose of them, as instructed by Atara; and
- (e) [ \* ].

Notwithstanding anything to the contrary herein, (a) upon delivery by a Party of notice of termination of this Agreement or expiration of this Agreement the remaining balance of the [ \* ] (if any) shall be deemed fully and finally satisfied; and (b) termination or expiration of this Agreement in whole or in part will be without prejudice to (i) Manufacturer's right to receive all fees and expenses accrued and unpaid through such expiration or the Termination Effective Date other than such fees and expenses disputed by Atara in good faith and with reasonable justification, including amounts set forth in Section 14.6 or (ii) any provisions that expressly or necessarily call for performance (including the Manufacturer's right to reimbursement for fees and expenses incurred in connection with such performance) after such termination or expiration.

14.5 **Return of Materials/Confidential Information.** Upon the earlier of the request of Discloser or the expiration or termination of this Agreement for any reason, Recipient agrees, except as otherwise provided in this Agreement and to the extent not prohibited by Applicable Law, to return to Discloser all documentation or other tangible evidence or embodiment of Discloser's Confidential Information that is not required by law to be retained by the Recipient and not to use such Confidential Information, unless otherwise agreed by the Parties in writing. [ \* ]. Manufacturer will also [ \* ] return all Atara Materials, Atara Equipment, retained samples, data, reports and other property, information and know-how in recorded form that was provided by Atara, or developed in the performance of the Services, that are owned by or licensed to Atara; provided that Atara will be responsible for all reasonable and documented costs and expenses associated with the return to Atara of Atara Materials, Atara Equipment and/or Atara Confidential Information by Manufacturer pursuant to this Agreement. Upon the written request of Manufacturer, Atara will destroy or return to Manufacturer (as requested by Manufacturer) all tangible copies, extracts or other representations of any portion of any Manufacturer Confidential Information that Atara comes into possession of as a result of Atara's [ \* ], and other representatives' or agents' access to the Facility or Manufacturer Confidential Information pursuant to Section 5.2(d).

14.6 **Inventories; Close-Out Amounts.** Upon expiration or termination of this Agreement or a pending Work Order: (a) Manufacturer shall [ \* ] complete and Atara shall pay for the services and activities (including completion of any work in process) agreed to pursuant to Section 14.4(e) to close out any pending Work Orders and Atara shall purchase from Manufacturer Product ordered under this Agreement (other than any [ \* ] that cannot be used for any purpose) at the price and in accordance with the payment schedule for such Product and services and activities, in each case as set forth in the applicable Work Order(s); (b) Atara shall pay all non-cancelable out-of-pocket expenses made in connection with any pending Work Order(s) through the Termination Effective Date and actually incurred by Manufacturer; (c) pay, through the Termination Effective Date all (i) [ \* ] and (ii) applicable [ \* ] for [ \* ] ordered. Following the Termination Effective Date, in accordance with Section 14.1, the terms and conditions of this Agreement that are applicable to any pending or active Work Orders shall continue to apply and for so long as Manufacturer continues to provide Services to Atara under such Work Orders, Atara will continue to pay for Services rendered and applicable [ \* ] for the [ \* ] used to perform Services, pro-rated to reflect the number of [ \* ] (and [ \* ] of [ \* ]) used by Manufacturer to perform such Services during such period.

14.7 **Payment Reconciliation.** Within [ \* ] after the close-out of a Work Order, Manufacturer will provide to Atara a written statement of all work performed by it in connection with the terminated Work Order, breakdown of the costs associated with that work, and a final invoice for that Work Order. [ \* ].

14.8 **Survival.** Expiration or termination of this Agreement (or any Work Order) for any reason will not relieve either Party of any right or obligation accruing prior to such expiration or termination through the Termination Effective Date. Further, (a) the provisions of [ \* ], (b) the provisions of all sections that must survive to permit Manufacturer to perform Services requested by Atara following the Termination Effective Date, and (c) any obligation, or liability of either Party under this Agreement or under any ancillary agreement executed in connection herewith, or any subsequent addenda hereto or thereto that by its nature and intent remains valid after termination or expiration will survive the Termination Effective Date or expiration of this Agreement. Covenants will expire in accordance with their respective terms and Sections 11.1 and 11.2 will survive until [ \* ] of such termination or expiration.

## 15. **Miscellaneous.**

15.1 **Independent Contractor.** All Services will be rendered by Manufacturer as an independent contractor for federal, state and local income tax purposes and for all other purposes. Manufacturer will not in any way represent itself to be a partner or joint venturer of or with Atara. This Agreement does not create an employer-employee relationship between Atara on the one hand and Manufacturer or any employee, subcontractors, Affiliate of Manufacturer, or any Manufacturer personnel on the other. Manufacturer is acting under this Agreement as an independent contractor with full power and authority to determine the means, manner and method of performance of Manufacturer's duties. Manufacturer will be responsible for and will withhold and/or pay any and all applicable federal, state or local taxes, payroll taxes, workers' compensation contributions, unemployment insurance contributions, or other payroll deductions from the compensation of Manufacturer's employees and other Manufacturer personnel. Manufacturer understands and agrees that it is solely responsible for such matters in the prior sentence and that it will indemnify Atara and hold Atara harmless from all claims and demands in connection with such matters. Neither Party hereto will have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party or to bind the other Party to any contract, agreement or undertaking unless expressly so authorized in writing by the other Party.

15.2 **Force Majeure.** Except as otherwise expressly set forth in this Agreement, neither Party will have breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of

the affected Party, including fire, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, acts of God or acts, omissions, or delays in acting, by any governmental authority (“*force majeure*”). The Party affected by any event of *force majeure* will promptly notify the other Party, explaining the nature, details and expected duration of the *force majeure* event. Such Party will also notify the other Party from time to time as to when the affected Party reasonably expects to resume performance in whole or in part of its obligations under this Agreement, and to notify the other Party of the cessation of any such event. A Party affected by an event of *force majeure* will use its [ \* ] to remedy, remove, or mitigate such event and the effects of it with all reasonable dispatch. If a Party anticipates that an event of *force majeure* may occur, such Party will notify the other Party of the nature, details and expected duration of the *force majeure* event. Upon termination of the event of *force majeure*, the performance of any suspended obligation or duty will promptly recommence.

15.3 **Public Statements.** Except to the extent required by applicable law or regulation or the rules of any stock exchange or listing agency, neither Party will make any public statement or release concerning this Agreement or the transactions contemplated by this Agreement, or use the other Party’s name or the name of any Affiliate of the other Party in any form of advertising, promotion or publicity, without obtaining the prior written consent of such Party.

15.4 **Notices.** All notices must be in writing and sent to the address for the recipient set forth in this Agreement below or at such other address as the recipient may specify in writing under this procedure. All notices must be given by (a) personal delivery, with receipt acknowledged; or (b) prepaid certified or registered mail, return receipt requested; (c) electronic mail or (d) prepaid recognized next Business Day or express delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

If to Manufacturer, to:  
4600 E. Shelby Drive, Suite 108  
Memphis, TN 38118  
Attention: [ \* ], Chief Executive Officer

If to Atara, to:  
611 Gateway Blvd., Suite 900  
South San Francisco, CA 94080  
Attention: Executive Vice President, Chief Technical Operations Officer

15.5 **Binding Agreement; Assignment.** This Agreement will bind and inure to the benefit of the Parties and their respective successors, heirs, and assigns. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part, (a) in connection with the transfer or sale of all or substantially all of its assets or the line of business or Product to which this Agreement relates; (b) to a successor entity or acquirer in the event of a merger, consolidation or change of control; or (c) to any Affiliate capable of meeting its financial obligations under this Agreement, as determined in good faith by the non-assigning Party. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume the rights and obligations of its assignor under this Agreement.

15.6 **Entire Agreement.** This Agreement, together with the attached Appendices and any fully-signed Work Orders, Quality Agreements and Change Orders, each of which are incorporated into this Agreement, constitute the entire agreement between the Parties with respect to the specific subject matter of this Agreement and all prior and contemporaneous agreements with respect such subject matter are superseded, including without limitation, the DMSA.

15.7 **No Modification.** This Agreement and/or any Work Order or Quality Agreement may be changed only by a writing signed by authorized representatives of each Party.

15.8 **Severability; Reformation.** Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, within the limits of applicable laws, rules or regulations.

15.9 **Governing Law.** This Agreement and any disputes arising out of or relating to this Agreement is governed by, construed and interpreted in accordance with the internal laws of the laws of the State of New York, U.S.A., without regard to any choice of law principle that would require the application of the law of another jurisdiction. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980. This provision will operate without prejudice to either Party's ability to seek injunctive or other interlocutory relief in any court accepting jurisdiction to protect and enforce its intellectual property rights. Notwithstanding any provision to the contrary, any actions taken by Manufacturer or refrained from by Manufacturer as are required to permit Manufacturer to comply with law, rule or regulation, including under any Work Order or the Quality Agreement is not and will not be deemed a breach of any Manufacturer obligation hereunder. Without limiting the preceding sentence, Manufacturer will work with Atara in good faith to perform any Services requested by Atara in writing that would permit Atara to use Product pursuant to the permission of the applicable competent Authority.

15.10 **Waiver.** Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

15.11 **No Benefit to Third Parties.** The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons.

15.12 **No Strict Construction; Headings.** This Agreement has been prepared jointly and will not be strictly construed against either Party. The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement. The words "include," "includes" and "including" when used in this Agreement are deemed to be followed by the phrase "but not limited to". Whenever this Agreement refers to a request, such request must be in writing.

15.13 **Certain Regulatory Filings.** Not less than [ \* ] prior to filing with any relevant Authority any clinical trial application including any IND or EU Investigational Medicinal Product Dossier or any documentation that is comparable to such an application, Atara will give Manufacturer a copy of the relevant portions of the chemistry manufacturing controls (CMC) section of the common technical document or any comparable document that relates to any such application (all such documentation herein referred to as the "Application"). This disclosure will permit Manufacturer to verify that such portions of the Application accurately describes the Services that Manufacturer has performed and the manufacturing and testing processes that Manufacturer will perform under this Agreement.

15.14                    **SEC Filings.** If Atara determines that it is legally required to file this Agreement with the Securities and Exchange Commission (SEC), Atara will use [ \* ] to seek confidential treatment of the terms of this Agreement pursuant to Applicable Law, it being understood that the SEC ultimately will decide whether to grant such request for confidential treatment. Atara will provide the draft confidential treatment request to Manufacturer with the proposed filing at least [ \* ] in advance of submission and will in good faith make [ \* ] to redact any such filing in accordance with Manufacturer's reasonable instructions.

15.15                    **Remedies.** Termination of this Agreement by a Party will not be an exclusive remedy and all other remedies will be available to the terminating Party, in equity and at law. If any set of facts or circumstances form the basis of a claim under more than one provision in this Agreement (including, for clarity, any Work Order and/or any Quality Agreement), either Party may pursue relief under any or all of such provisions, but in no event will either Party be entitled to duplicate or multiple recovery for any loss arising from or relating to the same set of facts or circumstances.

15.16                    **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument.

**[Remainder of page left blank intentionally]**



## APPENDIX A

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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## APPENDIX B

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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## APPENDIX C

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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## APPENDIX D

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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## APPENDIX E

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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## APPENDIX F

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

**LIST OF SUBSIDIARIES**

The following is a list of subsidiaries of the Company as of December 31, 2019:

<u>Subsidiary Legal Name</u>	<u>State or other Jurisdiction of Incorporation or Organization</u>
Atara Biotherapeutics Australia Pty. Ltd.	Australia
Atara Biotherapeutics Ireland Limited	Ireland
Atara Biotherapeutics Netherlands B.V.	Netherlands
Atara Biotherapeutics Switzerland GmbH	Switzerland

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statements No. 333-223262 on Form S-3; and No. 333-199508, No. 333-204076, No. 333-209961, No. 333-214431, No. 333-219763, No. 333-223254, and No. 333-229861 on Form S-8 of our reports dated February 27, 2020, 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, 2019.

/s/ *DELOITTE & TOUCHE LLP*

San Jose, California  
February 27, 2020

**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: February 27, 2020

/s/ Pascal Touchon

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Pascal Touchon  
President and Chief Executive Officer  
(Principal Executive Officer)



**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: February 27, 2020

/s/ Utpal Koppikar  
\_\_\_\_\_  
Utpal Koppikar  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**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, 2019, 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: February 27, 2020

/s/ Pascal Touchon

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Pascal Touchon  
President and Chief Executive Officer  
(Principal Executive Officer)

/s/ Utpal Koppikar

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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.