

**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, 2018

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: Common Stock, par value \$0.0001 per share, traded on The Nasdaq Stock Market

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer

Non-accelerated filer Small reporting company

Emerging growth company

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

Indicate by check mark whether the Registrant 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 29, 2018 as reported by The Nasdaq Stock Market, was \$1,076,600,732. This calculation excludes 16,038,673 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 15, 2019 was 46,161,657.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2019 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.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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 use, sales;
- our ability to sell or manufacture approved products at commercially reasonable values; and
- timing and costs related to qualification of our manufacturing plant.

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 platform consists of:

- our own scientific, clinical and regulatory expertise and know-how;
- 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;
- the Atara T-Cell Operations and Manufacturing facility, or ATOM, our recently constructed manufacturing facility which is capable of producing multiple types of therapies; and
- Atara MatchMe™, our proprietary, web-based, off-the-shelf delivery solution which will serve as a portal for order input, tracking, execution of our cell selection algorithm, product shipment and tracking.

Atara's most advanced T-cell immunotherapy, tab-cel® (tabelecleucel), is in Phase 3 development for patients with Epstein-Barr virus, or EBV, associated post-transplant lymphoproliferative disorder, or EBV+ PTLD, who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma, or NPC. Atara is also developing T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis, or MS (ATA188 and ATA190). Atara's pipeline also includes next-generation CAR T immunotherapies for patients with hematologic malignancies and solid tumors, autoimmune and viral diseases, including ATA2271 targeting mesothelin, ATA2321 for patients with acute myeloid leukemia, or AML, and ATA2431 and ATA3219 for patients with B-cell lymphomas. In addition to these core programs, we also have a diverse pipeline of other programs including ATA621 directed against the BK and JC viruses, ATA368 for patients with human papillomavirus, or HPV, associated cancers, ATA520 for patients with Wilms Tumor 1, or WT1, associated cancers and ATA230 directed against cytomegalovirus, or CMV, related diseases.

In June 2018, we opened our dedicated and expandable Atara T-Cell Operations and Manufacturing facility, or ATOM, in Thousand Oaks, California. ATOM has the flexibility to produce multiple T-cell and CAR T immunotherapies and integrates research and process science to enable rapid development. The research and development and process and analytical development labs at ATOM are operationally supporting preclinical development activities. ATOM is designed to global regulatory standards, and the commissioning and qualification activities required to support ATOM manufacturing capacity to support clinical production are expected to be completed in 2019.

Our Technology and Pipeline

Our pipeline is summarized below:

	Indication/Program	Target	Preclinical	Phase 1	Phase 2	Phase 3	Registration
Tab-cel® (tabelecleuce)	RR EBV+ PTLD following HCT	EBV		MATCH			
	RR EBV+ PTLD following SOT	EBV		ALLELE			
	Nasopharyngeal carcinoma ⁽¹⁾	EBV					
	EBV+ cancers ⁽²⁾	EBV					
Multiple sclerosis	Autologous ATA190: Progressive MS	EBV ⁽³⁾					
	Off-the-shelf, allogeneic ATA188: Progressive MS	EBV ⁽³⁾					
Next-gen CAR T	Solid tumors ⁽⁴⁻⁶⁾	Mesothelin					
	Acute myeloid leukemia ⁽⁴⁾	Dual undisclosed					
	B-cell malignancies ⁽⁴⁾	CD19-CD20-CD22					
	Off-the-shelf, allogeneic B-cell malignancies	CD19					

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

(2) Phase 2 basket study planned including EBV+ LMS, EBV+ PTLD with CNS involvement and other EBV+ cancers

(3) Targeted antigen recognition technology

(4) Development expected to start in autologous setting

(5) 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

(6) MSK investigator-sponsored Phase 1 study (NCT024114269) of a mesothelin-targeted CAR T immunotherapy is ongoing; Alara'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.

Technology Overview

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. 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 us to eliminate pre-treatment before our cells are administered and to reduce monitoring following administration. For example, in our ongoing studies, patients are monitored for one to two hours following receipt of tab-cel®.

Our T-cell immunotherapy platform is applicable to a broad array of targets and diseases. With more than 200 patients treated across the platform, we have observed clinical proof of concept across both viral and non-viral targets in conditions ranging from hematological malignancies and solid tumors to infectious and autoimmune diseases. We have also observed a safety profile characterized by few treatment-related serious adverse events, or SAEs, positive long-term outcomes including durable remissions, and no evidence of cytokine release syndrome to date.

Our allogeneic T-cell immunotherapy product candidates are bioengineered from cells donated by healthy individuals with normal immune function. Once cells are collected from a donor, they are bioengineered to recognize the antigens of interest and then expanded in number. The resulting expanded T-cells are then characterized and held as inventory. From inventory, these cells can be selected, distributed and prepared for infusion in a partially human leukocyte antigen-, or HLA-, matched patient within approximately three days. Following administration, our T cells are designed to home to their target, undergo target-dependent proliferation, eliminate diseased cells and eventually recede. Target-dependent proliferation means that our T cells expand in number when they encounter diseased cells in a patient's body that express the antigen the cells are designed to recognize. Our existing allogeneic process and know-how allow for minimal cell manipulation (single versus multiple genetic manipulations) which we believe will enable us to develop a new generation CAR T construct that includes multiple chimeric antigen receptors, or CARs, per cell and CAR designs that will enhance persistence and efficacy.

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.

Tab-cel® for EBV+ PTLD Following HCT or SOT

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 70% 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.

We licensed certain patent rights, know-how and a library of T cells and cell lines specific to EBV, CMV and WT1 from MSK in June 2015 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 currently being investigated for the treatment of patients with EBV+ PTLD who have failed rituximab or rituximab plus chemotherapy. 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. In December 2016, we announced that we had reached agreement with the FDA on the designs of two Phase 3 studies for tab-cel® intended to support approval in two separate indications, the treatment of EBV+ PTLD following HCT (which we refer to as the MATCH study) and SOT in patients who have failed rituximab (which we refer to as the ALLELE study). In December 2017, following discussion with the FDA of manufacturing and comparability data generated on material manufactured by our contract manufacturing organization, we initiated these studies in the U.S. We expect to expand these studies geographically to include clinical sites outside the U.S. Discussions with the FDA regarding the development of tab-cel® are ongoing and our intention is to reach alignment on a global regulatory strategy for patients with EBV+ PTLD. Outcomes of these discussions are expected in the first half of 2019.

The Phase 3 MATCH study is a multicenter, open label, single arm study currently designed to enroll approximately 35 patients with EBV+ PTLD following HCT who have failed rituximab. The Phase 3 ALLELE study is a multicenter, open label study currently designed with two non-comparative cohorts of approximately 35 patients each. The first cohort includes patients who previously received rituximab monotherapy, and the second cohort includes patients who previously received rituximab plus chemotherapy. Both cohorts are enrolling concurrently. The primary endpoint of both the MATCH and ALLELE studies is 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. The current protocols are 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 35 patients in MATCH, an observed ORR above approximately 37% would be expected to meet the primary endpoint. ALLELE is currently designed such that each of the two cohorts will be analyzed separately with respect to the primary endpoint and, as an example, with 35 patients enrolled in either cohort, an observed ORR above approximately 37% would be expected to meet the primary endpoint. Secondary endpoints for both studies include duration of response, overall survival, safety, quality of life metrics, and other measures to evaluate its health economic impact.

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.

We are also pursuing marketing approval of tab-cel® in the European Union. The EMA issued a positive opinion for orphan drug designation for tab-cel® for the treatment of patients with EBV+ PTLD and granted tab-cel® access to the EMA's PRIME regulatory initiative for the treatment of patients with EBV+ PTLD following HCT who have failed rituximab. PRIME provides early enhanced regulatory support to facilitate regulatory applications and accelerate the review of medicines that address a high unmet need. Discussions with the EMA regarding the development of tab-cel® are ongoing and our intention is to reach alignment on a global regulatory strategy for patients with EBV+ PTLD. Outcomes of these discussions are expected in the first half of 2019. We plan to submit a tab-cel® EU conditional marketing authorization, or CMA, application in the second half of 2019.

We anticipate that initial tab-cel® Phase 3 results to be available to the company in the first half of 2019. To ensure the integrity of the ongoing, open-label tab-cel® Phase 3 studies, we anticipate disclosing initial top-line EBV+ PTLD results in the second half of 2019 following submission of the EMA CMA application.

We are continuing our preparations to support the planned commercialization of tab-cel®. This includes the development of a proprietary, web-based, off-the-shelf delivery solution for commercial use that we call Atara MatchMe™. The Atara MatchMe™ system will be a portal for health care professionals and institutions that allows for order input, including the provision of required patient HLA and other information, the execution of our cell selection algorithm, product shipment and tracking and the capture of data on outcomes following treatment. We expect to pursue approvals in key geographies, including the U.S., Europe, Canada and Australia and may seek partners to aid in our commercialization efforts in select markets. In addition, we expect to pursue development of tab-cel® in earlier lines of therapy as well as in other EBV-associated diseases and malignancies.

We maintain a multicenter expanded access protocol, or EAP. The primary objective of this program is to provide tab-cel® monotherapy to patients with EBV-associated diseases or certain EBV+ malignancies for whom there are no other therapeutic options. Key secondary objectives include evaluation of efficacy and safety through a robust collection of data.

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 1/2 study will evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the combination and was initiated in the fourth quarter of 2018.

ATA188 and ATA190 for Multiple Sclerosis

MS is a chronic 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 prevalent cases of MS in the U.S. and EU each year.

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: secondary progressive MS, or SPMS, and primary progressive MS, or PPMS. Published reports indicate that together, SPMS and PPMS make up 30%-35% 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 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 through their expression of a cell surface marker known as CD20.

In October 2015 and September 2016, 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, which we refer to as the 2016 QIMR License Agreement, 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 disease.

Our T-cell immunotherapy product candidate utilizing this technology, ATA188 is an off-the-shelf EBV-specific T-cell preparation that utilizes a 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. We are also developing ATA190, an autologous EBV-specific T-cell preparation. ATA190 utilizes the same approach to targeted antigen recognition as ATA188. These product candidates are 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 ATA188 for patients with PMS and in January 2018 announced that we received clearance of our investigational new drug, or IND, application from the FDA to proceed with patient enrollment at U.S. sites. In the first quarter of 2018, we initiated this study in the U.S. 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 such as Expanded Disability Status Scale, or EDSS, and annualized relapse rate, or ARR, as well as MRI imaging. We expect initial safety results from the ongoing ATA188 study in the first half of 2019. Additional safety and efficacy results from this study are expected in the second half of 2019.

Our collaborating investigators at QIMR Berghofer have conducted a Phase 1 study utilizing autologous ATA190 for the treatment of patients with PMS. Based on the Phase 1 clinical results observed to date with ATA190, we believe the continued development of ATA190 will enhance our understanding of the potential therapeutic utility of targeting EBV in the treatment of MS and further inform and complement our development of ATA188. We plan to initiate a randomized ATA190 study in PMS patients in the second half of 2019.

We expect to broadly explore the utility of our targeted antigen recognition technology in EBV-related and other virally driven diseases, and additional product candidates derived from our collaboration with QIMR Berghofer are being developed. As part of our collaboration with QIMR Berghofer, we entered into a research and development collaboration agreement, which requires us to reimburse the cost of agreed-upon development activities related to the collaboration and also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones.

Next-Generation CAR T Program




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 allogeneic CAR T program targeting mesothelin. In our CAR T agreements with MSK, 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.

In August 2018, we entered into a strategic collaboration with Moffitt to develop multi-targeted CAR T immunotherapies for patients with AML (ATA2321) and B cell malignancies (ATA2431). 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 AML and B-cell malignancies, 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 based on CD28 and 4-1BB that may improve CAR T proliferation when responding to an appropriate antigen and enhance CAR T persistence by reducing T-cell exhaustion.

We are rapidly advancing our CAR T pipeline across multiple therapeutic areas and expect results to be presented at upcoming scientific conferences. The first IND submission for our next-generation CAR T program is expected in the fourth quarter of 2019 or the first quarter of 2020.

In addition to our partnered CAR T programs, we are also pursuing an internal allogeneic CD19 program.

Our next-generation CAR T oncology pipeline is summarized below:

Program	Indication	Target	CAR T Technologies	Collaborator
ATA2271	Solid tumors	Mesothelin	PD-1 DNR Novel 1XX co-stimulation domain ⁽¹⁾	 Memorial Sloan Kettering Cancer Center
ATA2321	Acute Myeloid Leukemia (AML)	Dual-targeted undisclosed	Novel co-stimulation domains ⁽¹⁾	 MOFFITT CANCER CENTER
ATA2431	B-cell malignancies	CD19-CD20-CD22	Novel co-stimulation domains ⁽¹⁾	 MOFFITT CANCER CENTER
ATA3219	B-cell malignancies	CD19	Off-the-shelf, allogeneic Novel co-stimulation domain	None

(1) Development expected to start in autologous setting

Additional Platform Expansion Activities

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 potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and public and private research institutions. Some of these potential competitors may have a more established presence in the market and significantly greater financial, technical and human resources than we have. Our commercial opportunity 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+ PTLD

There are currently no FDA- or EMA-approved products for the treatment of EBV+ PTLD. However, some approved 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: Viracta Therapeutics, Inc., which is conducting a Phase 1b/2 clinical study for tractinostat (VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas, ViraCyte, LLC, which is conducting a Phase 2 clinical study for Viralym-M™, an allogeneic, multi-virus T-cell product that targets five viruses including EBV and Tessa Therapeutics Pte Ltd., or Tessa, which is conducting a Phase 1 clinical study of MABEL CTLs, an allogeneic T-cell therapy in relapsed/ refractory EBV+ lymphomas.

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, relatilimab and daratumumab, Roche Pharmaceuticals' bevacizumab and AstraZeneca PLC's tremelimumab.

Multiple Sclerosis

Competition in the MS market is high with at least 16 therapies, including three generics, approved for the treatment of RRMS in the U.S. and European Union. There are many U.S. and international competitors in the RRMS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Ocrevus®, marketed by Roche Pharmaceuticals, was approved for the treatment of relapsing MS in the U.S. and European Union. There are numerous development candidates in Phase 3 studies for RRMS including Novartis International AG's, or Novartis, anti-CD20 monoclonal antibody ofatumumab, TG Therapeutics' anti-CD20 monoclonal antibody ublituximab and J&J/Actelion's next-generation sphingosine 1-phosphate receptor (S1PR) agonist ponesimod. There are also several therapeutic candidates awaiting FDA or EMA regulatory approval including EMD Serono's cladribine, a lymphocyte-targeting agent, Biogen's diroximel fumarate, a next-generation oral fumarate and Celgene's ozanimod, an S1PR and S1PR5 agonist.

Only three therapies have been approved for the treatment of PMS. Recently, Ocrevus® was approved in the U.S. and European Union for the treatment of PPMS. Extavia® (marketed by Novartis) and Betaseron® (marketed by Bayer AG) are approved in the European Union for the treatment of SPMS. In the U.S., there is one drug (mitoxantrone) approved to treat SPMS, which is now generic. Novartis has filed marketing applications for siponimod in SPMS in both the U.S. and EU and is on track for launches in 2019.

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's ibudilast (MN166), a non-selective PDE inhibitor is in Phase 2 studies for primary and 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 Sciences, Inc.'s and Kite Pharma's Yescarta (axicabtagene ciloleucel). However, given the explosion of innovation in this area, there are more than 100 CAR Ts in development with more than 35 being allogeneic and off-the-shelf cell therapies. In addition, depending on the diseases that our CAR T therapies target, we may face competition in the indication of interest from both CART therapies and other modalities such as small molecules and antibodies.

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 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.

QIMR Berghofer License Agreement and Research and Development Collaboration Agreement

In September 2016, we entered into the 2016 QIMR License Agreement and an amended and restated research and development collaboration agreement, or the 2016 QIMR Collaboration Agreement, with QIMR Berghofer, each of which amended and restated prior agreements entered into with QIMR Berghofer in October 2015. Under the 2016 QIMR License Agreement and 2016 QIMR Collaboration Agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell programs utilizing technology and know-how developed by QIMR Berghofer as well as the option to license additional technology in exchange for \$3.3 million in cash. We exercised this option in June 2018.

The 2016 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 2016 QIMR Collaboration Agreement, we are required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. The 2016 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 2016 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 2016 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 45 patent families having a total of more than 200 issued patents or patent applications. Our patents and patent applications (if issued) are expected to expire between 2022 and 2038, 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 11 different trademarks having a total of more than 100 trademark registrations and pending trademark applications.

Government Regulation

Regulatory Overview

Government authorities in the U.S. (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.

Overview of U.S. Government Regulation

Our product candidates, including tab-cel[®], are regulated by the FDA as biologics which are reviewed by the Center for Biological Evaluation and Research. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with current good manufacturing practices, 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 studies to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization.

Failure to comply with FDA requirements, either before and after product approval, may subject us or our partners, contract manufacturers, and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and criminal prosecution.

The steps required before a biologic may be approved for marketing of an indication in the U.S. generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practices, or GLP, and other applicable regulations;
- submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical studies may commence;
- completion of adequate and well-controlled human clinical studies in accordance with good clinical practices, or GCP, to establish that the biological product is “safe, pure and potent”, which is analogous to the safety and efficacy approval standard for a chemical drug product for its intended use;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA preapproval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current good manufacturing practices, or cGMP and in the case of our T-cell immunotherapy product candidates, good tissue practices, or GTP; and
- FDA review of the BLA and issuance of a biologics license.

Before conducting studies in humans, laboratory evaluation of product chemistry, toxicity and formulation as well as animal studies to assess the potential safety and efficacy of the biologic candidate must be conducted. Preclinical toxicology studies in animals must be conducted in compliance with FDA regulations. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. In addition to including the results of the preclinical testing, the IND will also include a protocol detailing, among other things, the objectives of the clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase or phases of the clinical study lend themselves to an efficacy determination. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, places the IND on clinical hold because of safety concerns about the product candidate or the conduct of the study described in the clinical protocol included in the IND. The IND sponsor and the FDA must resolve any outstanding concerns before clinical studies can proceed.

All clinical studies for new drugs and biologics must be conducted under the supervision of one or more qualified principal investigators in accordance with GCP. They must be conducted under protocols detailing the objectives of the applicable phase of the study, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical studies must be submitted to the FDA annually. Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. An institutional review board, or IRB, at each institution participating in the clinical study must review and approve the protocol before a clinical study commences at that institution, approve the information regarding the study and the consent form that must be provided to each research subject or the subject's legal representative, and monitor the study until completed.

Clinical studies are typically conducted in three sequential phases, but the phases may overlap and different studies may be initiated with the same product candidate within the same phase of development in similar or differing patient populations.

Phase 1 clinical studies may be conducted in a limited number of patients or healthy volunteers, as appropriate. The product candidate is initially tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics.

Phase 2 usually involves studies in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the product candidate for specific, targeted indications to determine dosage tolerance and optimal dosage and to identify possible short-term adverse effects and safety risks.

Phase 3 studies are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Results from one study are not necessarily predictive of results from later studies. Furthermore, the FDA or the sponsor may suspend clinical studies at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

The results of the preclinical studies and clinical studies, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, the fees payable to the FDA for reviewing a BLA, as well as annual program fees for approved products, can be substantial but are subject to certain limited deferrals, waivers and reductions that may be available. The fees typically increase each year. Each BLA submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following receipt by the FDA of the application. If the BLA is found complete, the FDA will file the BLA, triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission.

The expected speed of FDA review depends on whether a BLA application is considered to be a standard application or a priority application. The circumstances under which an application may be considered a priority application are discussed below under the heading "Expedited Review and Approval". The FDA's established goal is to review 90% of priority BLA applications within six months after the application is accepted for filing and 90% of standard BLA applications within 10 months of the acceptance date, whereupon a review decision is to be made. The FDA, however, may not approve a product candidate within these established goals and its review goals are subject to change. Further, the outcome of the review, even if generally favorable, may not be an actual approval but a "complete response letter" that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facility or facilities at which the product is manufactured and will not approve the product unless the facility complies with cGMP. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can extend the review process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval may impose limitations on the uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies be conducted following approval as a condition of the approval, and may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. The FDA must approve a BLA supplement or a new BLA before a product may be marketed for other uses or before certain manufacturing or other changes may be made. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

Under the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, a statutory pathway has been created for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products licensed under the Public Health Service Act. The BPCIA also grants innovator manufacturers of original reference biological products 12 years of exclusivity before biosimilars can be approved for marketing in the U.S.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP and GTP requirements, as applicable and the FDA periodically inspects manufacturing facilities to assess compliance with these standards. Accordingly, manufacturers must continue to spend time, money and effort to maintain compliance.

Orphan Drug Act

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the U.S. at the time of application for orphan drug designation. Orphan drug designation must be requested before submitting a BLA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the holder of the approval is entitled to a seven-year exclusive marketing period in the U.S. for that product except in very limited circumstances. For example, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the U.S. during the seven-year exclusive marketing period. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

Legislation similar to the Orphan Drug Act has been enacted outside the U.S., including in the EU. The orphan legislation in the EU is available for therapies addressing chronic debilitating or life-threatening conditions that affect five or fewer out of 10,000 persons or are financially not viable to develop. The market exclusivity period in the EU is for 10 years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. The market exclusivity may be extended to 12 years if the sponsor completes a pediatric investigation plan agreed upon with the relevant committee of the EMA.

Expedited Review and Approval

The FDA has various programs, including Fast Track and Regenerative Medicine Advanced Therapy, or RMAT, priority review and accelerated approval, which are intended to expedite or simplify the process for developing and reviewing promising drugs, or to provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track and RMAT are processes designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of 10 months. Although Fast Track, RMAT and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track-designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical studies to confirm the clinically meaningful outcome as predicted by the surrogate marker study.

In addition to the Fast Track, RMAT, accelerated approval and priority review programs discussed above, breakthrough therapy designation may be pursued. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program; intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and rolling review.

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 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. The Texas U.S. District Court Judge, as well as the presidential administration and the Centers for Medicare and Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, but 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. 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.

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 European Union 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 European Union 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.

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

In June 2018, we opened our dedicated and expandable manufacturing facility, ATOM, in Thousand Oaks, California. ATOM has the flexibility to produce multiple T-cell and CAR T immunotherapies and integrates research and process science to enable rapid development. The research and development and process and analytical development labs at ATOM are operationally supporting preclinical development activities. ATOM is designed to global regulatory standards, and the commissioning and qualification activities required to support ATOM manufacturing capacity to support clinical production are expected to be completed in 2019.

In addition to ATOM, we also work with Cognate Bioservices, Inc., or Cognate, pursuant to a Development and Manufacturing Services Agreement, or Manufacturing Agreement, that we entered into in August 2015 and which was amended in December 2017 and May 2018. Pursuant to the Manufacturing Agreement, Cognate provides process development and manufacturing services for certain of our product candidates.

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 quarterly to ensure we are planning manufacturing capacity and capabilities accordingly across our network. Our manufacturing network is comprised of ATOM, the manufacturing capabilities of our partners 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. The manufacturing process involves co-culturing and incubating viral- or cancer-specific antigen transformed B cells collected from the third-party donated material along with T cells collected from the same donor. These 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, 2018, we had 311 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.

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.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. 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 and combined financial statements and related notes, together with our other filings made from time to time with the SEC 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, 2018, we reported a net loss of \$230.7 million and we had an accumulated deficit of \$527.3 million as of December 31, 2018.

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 complete our own 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 studies 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 studies 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 will be sufficient to fund our planned operations to mid-2020. As of December 31, 2018, we had total cash, cash equivalents and short-term investments of \$309.6 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, 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 studies, clinical studies and 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 studies 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 clinical-stage product candidates include tab-cel[®], ATA188 and ATA190. 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 studies 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 studies 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[®], ATA188 or ATA190, 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. For example, the primary endpoint of both the MATCH and ALLELE studies is “confirmed best objective response rate” 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 contrast, neither the prior MSK studies nor our EAP study protocol require response confirmation. The findings may not be reproducible in late phase studies we conduct. For instance, the current protocols for our MATCH and ALLELE studies are 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 35 patients in MATCH, an observed ORR above approximately 37% would be expected to meet the primary endpoint. ALLELE is currently designed such that each of the two cohorts will be analyzed separately with respect to the primary endpoint and, as an example, with 35 patients enrolled in either cohort, an observed ORR above approximately 37% would be expected to meet the primary endpoint. In addition, due to the nature of clinical study protocols, the study protocol is subject to further negotiation and discussion with regulators, and, with the approval of regulators, we may, for example, adjust the number of patients in a study, which could 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 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 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 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 studies 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. Many of our product candidates are designed to treat rare diseases, and as a result the pool of potential patients with respect to a given disease is small. We may not be able to initiate or continue to support clinical studies of tab-cel®, ATA188, ATA190 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.

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+ PTLN 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 BT, for tab-cel[®] for EBV+ PTL, 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 BT 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 BT 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, and 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 extremely 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.

In June 2018, we opened our Atara T-Cell Operations and Manufacturing, or ATOM, facility in Thousand Oaks, California. The research and development and process and analytical development labs are operationally supporting preclinical development activities. The facility commissioning and qualification activities required to support ATOM production were completed in Q4 2018. Product specific qualifications are ongoing to support both clinical and commercial production and are expected to be completed in 2019. If the appropriate regulatory approvals for the new 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 do not currently manufacture our product candidates in our own facilities and we rely on our CMO or our partners for the production of our product candidates and the acquisitions 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[®], ATA188, ATA190, 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. For example, we generated and evaluated data from new material manufactured by our CMO and identified certain assays that need refinement prior to initiating the Phase 3 studies of tab-cel[®]. We have generated comparability data from the cell lines produced by our CMO using our refined assays and believe this data supports the demonstration of comparability, and we recently initiated the Phase 3 studies in the U.S. following discussions with FDA.

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 the addition of the ATOM facility provides us with future flexibility within our manufacturing network, we still may need to identify additional CMOs for continued production of supply for some or all 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 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 preissuance 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 competitive 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.

Recently enacted 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 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. In December 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act. The Texas U.S. District Court Judge, as well as the presidential administration and the CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, but 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 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 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. 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 approved 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: Viracta Therapeutics, Inc., which is conducting a Phase 1b/2 clinical study for tractinostat (VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas, ViraCyte, LLC, which is conducting a Phase 2 clinical study for Viralym-M™, an allogeneic, multi-virus T-cell product that targets five viruses including EBV and Tessa Therapeutics Pte Ltd., or Tessa, which is conducting a Phase 1 clinical study of MABEL CTLs, an allogeneic T-cell therapy in relapsed/ refractory EBV+ lymphomas. In addition, Tessa is evaluating TT10, an autologous, EBV-specific T-cell product, in a phase 3 clinical study for advanced NPC.

Competition in the MS market is high with at least sixteen therapies, including three generics, approved for the treatment of relapsing-remitting multiple sclerosis (RRMS) in the U.S. and European Union. There are many U.S. and international competitors in the RRMS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Ocrevus®, marketed by F. Hoffmann-La Roche, was approved for the treatment of relapsing MS in the U.S. and European Union. There are numerous development candidates in Phase 3 studies for RRMS including Novartis' anti-CD20 monoclonal antibody ofatumumab; TG Therapeutics' anti-CD20 monoclonal antibody ublituximab and J&J/Actelion's next-generation sphingosine 1-phosphate receptor (S1PR) agonist ponesimod. There are also several therapeutic candidates awaiting FDA and/or EMA regulatory approval including EMD Serono's cladribine, a lymphocyte-targeting agent, Biogen's diroximel fumarate (Trade name - Vumerity, a next-generation oral fumarate) and Celgene's ozanimod, an S1PR and S1PR5 agonist.

Only three therapies have been approved for the treatment of progressive MS. Recently, Ocrevus® was approved in the U.S. and European Union for the treatment of primary progressive MS (PPMS). Extavia® (marketed by Novartis) and Betaseron® (marketed by Bayer AG) are approved in the European Union for the treatment of secondary progressive MS (SPMS). In the U.S., there is one drug (mitoxantrone) approved to treat SPMS, which is now generic. Novartis has filed marketing applications for siponimod in SPMS in both the U.S. and EU and is on track for launches in 2019.

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's ibudilast (MN166), a non-selective PDE inhibitor is in Phase 2 studies for primary and secondary progressive MS.

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. This pricing premium may make it difficult for us to differentiate our products from currently approved or commonly used therapies and impede adoption of our products, 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 will 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, 2018, we had 311 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 studies 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 studies 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 identify and hire a new Chief Executive Officer, to retain our executive officers and to attract, retain and motivate qualified personnel.

Isaac E. Ciechanover, M.D., our President and Chief Executive Officer, announced that he will step down as our President and Chief Executive Officer, effective as of the earlier of June 30, 2019 or the date of his successor’s appointment. While our Board of Directors has undertaken a search to find a chief executive officer to succeed Mr. Ciechanover, the inability to effectively identify a suitable successor could have a material adverse effect on our business.

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.

The U.S. tax reform bill passed in 2017 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 have completed our evaluation of the overall impact of The Tax Act on our effective tax rate and balance sheet through year end, and reflected the amounts in our financial statements. The Tax Act may have significant impacts in future periods and our business and financial condition could be adversely affected. The future impact of the Tax Act 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, 2018, we reported U.S. federal and state NOLs of approximately \$293.9 million and \$449.8 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, 2018 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 future ownership changes as a result of future 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 December 31, 2016 through December 31, 2018, the reported sale price of our common stock has fluctuated between \$11.80 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.

Effective December 31, 2018, we are no longer an “emerging growth company,” and the reduced reporting requirements applicable to “emerging growth companies” no longer apply, which increases our costs as a result of being a public company and places additional demands on management.

Effective December 31, 2018, we are no longer classified as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act. As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. Because we are no longer being classified as an “emerging growth company”, the cost of compliance with Section 404 has required, and will continue to require, us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if, in the future, material weaknesses are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material effect on our stated operating results. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting or financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm.

In addition, we have previously taken advantage of the JOBS Act’s reduced disclosure requirements applicable to “emerging growth companies” regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. Since we are no longer classified as an “emerging growth company,” we are no longer eligible for such reduced disclosure requirements and exemptions and as such, we are required to hold a say-on-pay vote and a say-on-frequency vote at our 2019 annual meeting of stockholders. As a result, we expect that because we are no longer classified as an “emerging growth company,” we will require additional attention from management with respect to our disclosures and will incur increased costs, which could include higher legal fees, accounting fees, consultant fees and fees associated with investor relations activities, among others.

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 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. We also lease office space in Westlake Village, California under a lease agreement that expires in April 2019.

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 15, 2019, there were 11 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

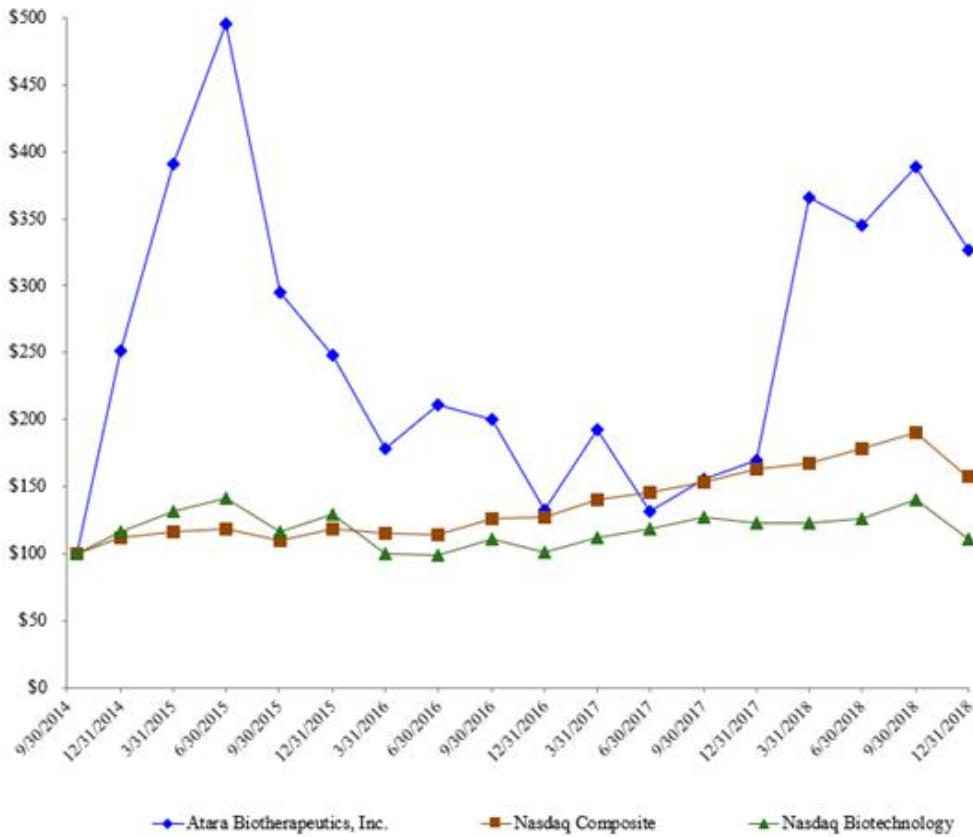
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Stock Performance Graph

Set forth below is a graph comparing the cumulative total return on an indexed basis of a \$100 investment in the Company’s common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index commencing on October 16, 2014 (the date our common stock began trading on The Nasdaq Global Select Market) and continuing through December 31, 2018. The graph assumes our closing sale price on October 16, 2014 of \$10.65 per share as the initial value of our common stock. Points on the graph represent the performance as of the last business day of each of the fiscal quarters indicated.

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 no indication of future performance.

COMPARISON OF CUMULATIVE TOTAL RETURN*



Among Atara Biotherapeutics, Inc., the Nasdaq Composite Index and the Nasdaq Biotechnology Index

* Assumes \$100 invested in our common stock or the related index on October 16, 2014.

Item 6. Selected Consolidated and Combined Financial Data

The following selected consolidated and combined financial data of the Company for each of the periods indicated are derived from the Company's audited consolidated and combined financial statements. The consolidated financial statements of the Company as of December 31, 2018 and 2017 and for the years ended December 31, 2018, 2017 and 2016, 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 and Combined Statements of Operations and Comprehensive Loss Data:	Year ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands, except per share amounts)				
Operating expenses:					
Research and development	\$ 167,457	\$ 81,206	\$ 56,514	\$ 41,618	\$ 15,446
General and administrative	69,654	40,326	24,728	16,830	12,710
Total operating expenses	237,111	121,532	81,242	58,448	28,156
Loss from operations	(237,111)	(121,532)	(81,242)	(58,448)	(28,156)
Interest and other income, net	6,368	2,027	2,203	1,218	125
Loss before income taxes	(230,743)	(119,505)	(79,039)	(57,230)	(28,031)
(Benefit from) provision for income taxes	(44)	(14)	10	(9)	(25)
Net loss	\$ (230,699)	\$ (119,491)	\$ (79,049)	\$ (57,221)	\$ (28,006)
Other comprehensive (loss) gain:					
Unrealized (loss) gain on available-for-sale securities	(189)	32	335	(418)	(100)
Comprehensive loss	\$ (230,888)	\$ (119,459)	\$ (78,714)	\$ (57,639)	\$ (28,106)
Basic and diluted net loss per common share	\$ (5.27)	\$ (4.00)	\$ (2.75)	\$ (2.24)	\$ (5.62)

Consolidated Balance Sheet Data:	As of December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Cash, cash equivalents and short-term investments	\$ 309,631	\$ 166,096	\$ 255,682	\$ 320,482	\$ 104,116
Working capital	\$ 281,510	\$ 144,544	\$ 250,878	\$ 314,888	\$ 103,302
Total assets	\$ 391,839	\$ 217,779	\$ 263,914	\$ 324,975	\$ 106,122
Long-term liabilities	\$ 13,003	\$ 12,269	\$ 503	\$ 166	\$ 216
Total stockholders' equity	\$ 338,857	\$ 177,864	\$ 253,736	\$ 315,100	\$ 103,182

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 platform consists of:

- our own scientific, clinical and regulatory expertise and know-how;
- 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;
- the Atara T-Cell Operations and Manufacturing facility, or ATOM, our recently constructed manufacturing facility which is capable of producing multiple types of therapies; and
- Atara MatchMe™, our proprietary, web-based, off-the-shelf delivery solution which will serve as a portal for order input, tracking, execution of our cell selection algorithm, product shipment and tracking.

Atara's most advanced T-cell immunotherapy, tab-cel® (tabeclcleucel), is in Phase 3 development for patients with Epstein-Barr virus, or EBV, associated post-transplant lymphoproliferative disorder, or EBV+ PTLD, who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma, or NPC. Atara is also developing T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis, or MS (ATA188 and ATA190). Atara's pipeline also includes next-generation CAR T immunotherapies for patients with hematologic malignancies and solid tumors, autoimmune and viral diseases, including ATA2271 targeting mesothelin, ATA2321 for patients with acute myeloid leukemia, or AML, and ATA2431 and ATA3219 for patients with B-cell lymphomas. In addition to these core programs, we also have a diverse pipeline of other programs including ATA621 directed against the BK and JC viruses, ATA368 for patients with human papillomavirus, or HPV, associated cancers, ATA520 for patients with Wilms Tumor 1, or WT1, associated cancers and ATA230 directed against cytomegalovirus, or CMV, related 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. 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 us to eliminate pre-treatment before our cells are administered and to reduce monitoring following administration. For example, in our ongoing studies, patients are monitored for one to two hours following receipt of tab-cel®.

Our T-cell immunotherapy platform is applicable to a broad array of targets and diseases. With more than 200 patients treated across the platform, we have observed clinical proof of concept across both viral and non-viral targets in conditions ranging from hematological malignancies and solid tumors to infectious and autoimmune diseases. We have also observed a safety profile characterized by few treatment-related serious adverse events, or SAEs, positive long-term outcomes including durable remissions, and no evidence of cytokine release syndrome to date.

Our allogeneic T-cell immunotherapy product candidates are bioengineered from cells donated by healthy individuals with normal immune function. Once cells are collected from a donor, they are bioengineered to recognize the antigens of interest and then expanded in number. The resulting expanded T-cells are then characterized and held as inventory. From inventory, these cells can be selected, distributed and prepared for infusion in a partially human leukocyte antigen-, or HLA-, matched patient within approximately three days. Following administration, our T cells are designed to home to their target, undergo target-dependent proliferation, eliminate diseased cells and eventually recede. Target-dependent proliferation means that our T cells expand in number when they encounter diseased cells in a patient's body that express the antigen the cells are designed to recognize. Our existing allogeneic process and know-how allow for minimal cell manipulation (single versus multiple genetic manipulations) which we believe will enable us to develop a new generation CAR T construct that includes multiple chimeric antigen receptors, or CARs, per cell and CAR designs that will enhance persistence and efficacy.

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.

In June 2018, we opened our dedicated and expandable Atara T-Cell Operations and Manufacturing facility, or ATOM, in Thousand Oaks, California. ATOM has the flexibility to produce multiple T-cell and CAR T immunotherapies and integrates research and process science to enable rapid development. The research and development and process and analytical development labs at ATOM are operationally supporting preclinical development activities. ATOM is designed to global regulatory standards, and the commissioning and qualification activities required to support ATOM manufacturing capacity to support clinical production are expected to be completed in 2019.

In addition to ATOM, we also work with Cognate Bioservices, Inc., or Cognate, pursuant to a Development and Manufacturing Services Agreement, or Manufacturing Agreement, that we entered into in August 2015 and which was amended in December 2017 and May 2018. Pursuant to the Manufacturing Agreement, Cognate provides process development and manufacturing services for certain of our product candidates.

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 studies 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 \$230.7 million, \$119.5 million and \$79.0 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$527.3 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, 2018, our cash, cash equivalents and short-term investments totaled \$309.6 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 clinical studies 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 facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

We plan to increase our research and development expenses as we continue 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 studies 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 ATA190 and enrolling patients to the Phase 1 study of ATA188 in MS;
- continuing to develop our product candidates in additional indications, including tab-cel[®] for NPC and EBV+ cancers;
- continuing to develop other product candidates, including ATA621 for BK and JC virus associated diseases; 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 as well as any 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 allocated information technology and facilities costs. We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount 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>Accrued Research and Development Expenses</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, 2018 and 2017, 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>

Stock-based Compensation		
<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 8 – “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 for employee awards and the date when the service performance is completed for non-employees. 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 employees’ 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 non-employees’ awards with performance-based vesting criteria, we assess all possible outcomes at the end of each reporting period and recognize the lowest aggregate fair value in the range of possible outcomes. The lowest value in the range of possible outcomes may be zero. 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 for awards with performance and other vesting criteria is recognized as expense under the accelerated graded vesting model.</p>	<p>Key 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.</p> <p>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 – 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 non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date.</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>

Accounting for Income Taxes		
See Note 9 – “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, 2018.	<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>	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 \$127.2 million as of December 31, 2018 related primarily to net operating losses, capitalized expenses and stock-based compensation.

Income Taxes

On December 22, 2017, the President signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. As of December 31, 2018, due to current year taxable losses and our federal valuation allowance position, we did not recognize any income tax expense or benefit as a result of enactment of the Tax Act. Due to accumulated foreign deficits the Company does not expect a current inclusion in U.S. federal taxable income for the transition tax on earnings of controlled foreign corporations.

The SEC staff has issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We consider the key estimates on the deferred tax remeasurement and the impact of the changes to the deductibility of executive compensation to be provisional due to expected forthcoming guidance from federal and state tax authorities, our continuing analysis of final year-end data and tax positions, as well as further guidance expected for the associated income tax accounting. During the year ended December 31, 2018, we did not make any adjustments to the provisional amounts included in the consolidated financial statements for the year ended December 31, 2017 with respect to either the change in corporate tax or executive compensation rule. As of December 31, 2018, we have finalized our analysis with respect to tax reform and no adjustments were required to be made as compared to the provisional amounts recorded as of December 31, 2017.

Emerging Growth Company Status

Until the end of 2018, we were an “emerging growth company” as defined in the JOBS Act, and therefore, we were able to take advantage of certain exemptions from various public company reporting requirements, including:

- the exemption from the requirement to obtain an attestation report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- less extensive disclosure about our executive compensation arrangements; and
- no requirement for stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We had, prior to ceasing to be an “emerging growth company,” irrevocably elected to opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards.

Effective December 31, 2018, we are deemed a “large accelerated filer” as our public float as of June 29, 2018 was greater than \$700 million, and thus we are no longer classified as an “emerging growth company.”

As such, we are no longer able to take advantage of the above exemptions, and in particular, are required to obtain an attestation report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act as of this date.

Results of Operations

Comparison of the Years Ended December 31, 2018, 2017 and 2016

Research and development expenses

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

	Year ended December 31,			Increase	
	2018	2017	2016	2018 compared to 2017	2017 compared to 2016
	(in thousands)				
Tab-cel® expenses	\$ 50,822	\$ 33,653	\$ 27,430	\$ 17,169	\$ 6,223
ATA188, ATA190 and other program expenses	30,155	9,243	3,746	20,912	5,497
Employee and overhead costs	86,480	38,310	25,338	48,170	12,972
Total research and development	<u>\$ 167,457</u>	<u>\$ 81,206</u>	<u>\$ 56,514</u>	<u>\$ 86,251</u>	<u>\$ 24,692</u>

Tab-cel® costs were \$50.8 million in 2018 as compared to \$33.7 million in 2017 and \$27.4 million in 2016. The increase in 2018 was primarily due to clinical study, manufacturing and outside service costs related to the two Phase 3 clinical studies of tab-cel® in patients with EBV+ PTLD who have failed rituximab, which were initiated in December 2017. The increase in 2017 was primarily due to manufacturing and outside service costs related to the preparation for these two Phase 3 clinical studies and ongoing costs for our tab-cel® EAP clinical study, which was initiated in mid-2016. We anticipate that tab-cel® costs will increase in 2019 due to continued enrollment in the two Phase 3 clinical studies as well as the initiation of the NPC study in the fourth quarter of 2018.

ATA188, ATA190 and other program costs were \$30.2 million in 2018 as compared to \$9.2 million in 2017 and \$3.7 million in 2016. 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 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 progressive MS. The increase in 2017 was primarily related to clinical manufacturing and preparations for the Phase 1 clinical study of ATA188, which was initiated in October 2017. We anticipate that ATA188, ATA190 and other program costs will remain relatively stable in 2019 primarily driven by an increase in manufacturing activity, the continued development of our manufacturing processes, clinical study activities, including the initiation of a randomized clinical study of ATA190, and development related to our collaborations with QIMR Berghofer and MSK offset by decrease in license fees incurred in 2018 not anticipated to recur in 2019.

Employee and overhead costs were \$86.5 million in 2018 as compared to \$38.3 million in 2017 and \$25.3 million in 2016. The increases of \$48.2 million in 2018 and \$13.0 million in 2017 were primarily a result of higher compensation-related costs from increased headcount in support of our continuing expansion of research and development activities. In particular, payroll and related costs increased by \$29.7 million in 2018 as compared to 2017, and by \$8.0 million in 2017 as compared to 2016, primarily due to increased headcount. Also, facility-related costs and professional services cost increased by \$10.6 million and \$7.9 million, respectively, in 2018 as compared to 2017, and by \$3.4 million and \$1.6 million, respectively, in 2017 as compared to 2016. These increases were primarily related to our continuing expansion of research and development activities. We anticipate that employee and overhead costs will continue to increase in future periods as we continue to expand such activities.

General and administrative expenses

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

	Year ended December 31,			Increase	
	2018	2017	2016	2018 compared to 2017	2017 compared to 2016
	(in thousands)				
General and administrative	<u>\$ 69,654</u>	<u>\$ 40,326</u>	<u>\$ 24,728</u>	<u>\$ 29,328</u>	<u>\$ 15,598</u>

General and administrative expenses were \$69.7 million in 2018 compared to \$40.3 million in 2017 and \$24.7 million in 2016. 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, a \$17.3 million increase in professional services costs, partially offset by a \$1.2 million decrease in facility-related costs. The increase of \$15.6 million in 2017 was primarily due to a \$10.0 million increase in compensation-related costs driven by increased headcount, a \$5.9 million increase in professional services costs, partially offset by a \$0.3 million decrease in facility-related costs. We expect that general and administrative costs will increase moderately in 2019.

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, 2018. 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
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 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 (loss) gain:				
Unrealized (loss) gain 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)

	Three months ended			
	March 31	June 30	September 30	December 31
2017	(In thousands, except per share amounts)			
Operating expenses:				
Research and development	\$ 17,541	\$ 18,296	\$ 20,598	\$ 24,771
General and administrative	8,620	9,613	11,062	11,031
Total operating expenses	26,161	27,909	31,660	35,802
Loss from operations	(26,161)	(27,909)	(31,660)	(35,802)
Interest and other income, net	509	481	564	473
Loss before income taxes	(25,652)	(27,428)	(31,096)	(35,329)
Provision for (benefit from) income taxes	2	—	—	(16)
Net loss	(25,654)	(27,428)	(31,096)	(35,313)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	31	38	26	(63)
Comprehensive loss	\$ (25,623)	\$ (27,390)	\$ (31,070)	\$ (35,376)
Basic and diluted net loss per common share	\$ (0.88)	\$ (0.94)	\$ (1.02)	\$ (1.15)

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common and preferred stock. 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 March 2017, we entered into a sales agreement, or the ATM Facility, with Cowen and Company, LLC, or Cowen, for the sale, in our sole discretion, of shares of our common stock, having an aggregate offering price of up to \$75.0 million through Cowen, as our sales agent. We paid Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold under the ATM Facility.

During the fiscal year ended December 31, 2018, we sold an aggregate of 1,007,806 shares of common stock under the ATM Facility, at an average price of approximately \$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. The issuance and sale of these shares by us pursuant to the ATM Facility are deemed “at the market” offerings and are registered under the Securities Act of 1933, as amended. As of December 31, 2018, we had approximately \$6.1 million of common stock remaining to be sold under the ATM Facility.

In February 2019, we terminated the ATM Facility and entered into a new sales agreement, or the New 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 issuance and sale of these shares by us pursuant to the New 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 New ATM Facility.

We have incurred losses and negative cash flows from operations in each year since inception. As of December 31, 2018, we had an accumulated deficit of \$527.3 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 research and development and general and administrative expenses will continue to increase and, 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 New ATM Facility. 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. Management expects that existing cash, cash equivalents and short-term investments as of December 31, 2018 will be sufficient to fund our planned operations to mid-2020.

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

	December 31, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	\$ 60,698	\$ 79,223
Short-term investments	248,933	86,873
Total cash, cash equivalents and short-term investments	<u>\$ 309,631</u>	<u>\$ 166,096</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,		
	2018	2017	2016
	(in thousands)		
Net cash provided by (used in):			
Operating activities	\$ (179,772)	\$ (87,502)	\$ (60,025)
Investing activities	(196,289)	99,909	83,741
Financing activities	357,536	20,048	506
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (18,525)</u>	<u>\$ 32,455</u>	<u>\$ 24,222</u>

Operating activities

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, 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.

Net cash used in operating activities was \$87.5 million in 2017 as compared to \$60.0 million in 2016. The increase of \$27.5 million was primarily due to a \$40.4 million increase in net loss, partially offset by a \$6.3 million increase stock-based compensation and an increase in changes in operating assets and liabilities of \$7.9 million.

Investing activities

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 \$196.3 million received from maturities and \$109.8 million from sales of available-for-sale securities.

Net cash provided by investing activities in 2017 consisted primarily of \$189.0 million received from maturities and \$107.6 million from 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.

Net cash provided by investing activities in 2016 consisted primarily of \$149.0 million received from maturities and \$242.6 million from sales of available-for-sale securities, partially offset by \$304.9 million used to purchase available-for-sale securities and \$3.0 million used to purchase property and equipment.

Financing activities

Net cash provided by financing activities in the 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 ATM Facility and \$24.7 million of net proceeds from employee stock transactions, partially offset by \$7.5 million of taxes paid related to the net share settlement of restricted stock and \$0.5 million on principal payments on capital lease obligations.

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

Net cash provided by financing activities in 2016 of \$0.5 million consists primarily of net proceeds from employee stock transactions.

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 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 will be sufficient to fund our planned operations to mid-2020. 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 studies 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 or other similar arrangements that we may enter into;
- 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 extent and timing of capital expenditures.

Contractual Obligations and Commitments

We lease our current 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 January 2015, we entered into a non-cancellable lease agreement for office and laboratory space in Westlake Village, California. In September 2015, we amended the lease agreement to add additional office space and extend the term of the agreement to April 2019. We intend to let this lease expire by its terms.

In February 2017, we entered into a lease agreement for ATOM, consisting of 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 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 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.

Aggregate future minimum commitments for our leases as of December 31, 2018 are as follows:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	\$ 10,162	\$ 1,107	\$ 3,221	\$ 2,712	\$ 3,122
Finance lease obligations	16,416	934	1,953	2,071	11,458
Capital lease obligations	803	540	263	—	—
Total contractual obligations	<u>\$ 27,381</u>	<u>\$ 2,581</u>	<u>\$ 5,437</u>	<u>\$ 4,783</u>	<u>\$ 14,580</u>

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.

We may also 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. Payments in the table above are based on current operating forecasts, which are subject to change, and do not include any termination fees.

Off-Balance Sheet Arrangements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate and Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2018, we had total cash, cash equivalents and short-term investments of \$309.6 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

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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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 26, 2019 expressed an unqualified opinion on the Company’s internal control over financial reporting.

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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

San Jose, California
February 26, 2019

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

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,698	\$ 79,223
Short-term investments	248,933	86,873
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	11,664	5,900
Total current assets	321,489	172,190
Property and equipment, net	68,576	44,129
Restricted cash - long-term	1,200	1,200
Other assets	574	260
Total assets	\$ 391,839	\$ 217,779
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,719	\$ 14,711
Accrued compensation	10,636	5,664
Accrued research and development expenses	19,210	4,006
Other current liabilities	6,414	3,265
Total current liabilities	39,979	27,646
Long-term liabilities	13,003	12,269
Total liabilities	52,982	39,915
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock—\$0.0001 par value, 500,000 shares authorized as of December 31, 2018 and 2017; 45,951 and 30,730 shares issued and outstanding as of December 31, 2018 and 2017, respectively	5	3
Additional paid-in capital	866,541	474,662
Accumulated other comprehensive loss	(340)	(151)
Accumulated deficit	(527,349)	(296,650)
Total stockholders' equity	338,857	177,864
Total liabilities and stockholders' equity	\$ 391,839	\$ 217,779

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

	Years Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development	\$ 167,457	\$ 81,206	\$ 56,514
General and administrative	69,654	40,326	24,728
Total operating expenses	<u>237,111</u>	<u>121,532</u>	<u>81,242</u>
Loss from operations	(237,111)	(121,532)	(81,242)
Interest and other income, net	6,368	2,027	2,203
Loss before income taxes	(230,743)	(119,505)	(79,039)
(Benefit from) provision for income taxes	(44)	(14)	10
Net loss	<u>\$ (230,699)</u>	<u>\$ (119,491)</u>	<u>\$ (79,049)</u>
Other comprehensive (loss) gain:			
Unrealized (loss) gain on available-for-sale securities	(189)	32	335
Comprehensive loss	<u>\$ (230,888)</u>	<u>\$ (119,459)</u>	<u>\$ (78,714)</u>
Net loss per common share:			
Basic and diluted net loss per common share	<u>\$ (5.27)</u>	<u>\$ (4.00)</u>	<u>\$ (2.75)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>43,811</u>	<u>29,863</u>	<u>28,732</u>

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

	Common Stock		Additional Paid-in Capital	Accumulated	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount		Other Comprehensive Loss		
Balance as of December 31, 2015	28,459	\$ 3	\$ 413,725	\$ (518)	\$ (98,110)	\$ 315,100
Issuance of common stock upon vesting of restricted stock awards	233	—	60	—	—	60
RSU settlements, net of shares withheld	199	—	(94)	—	—	(94)
Issuance of common stock pursuant to employee stock awards	42	—	600	—	—	600
Stock-based compensation expense	—	—	16,784	—	—	16,784
Net loss	—	—	—	—	(79,049)	(79,049)
Unrealized gain on available-for-sale securities	—	—	—	335	—	335
Balance as of December 31, 2016	28,933	3	431,075	(183)	(177,159)	253,736
Issuance of common stock through ATM Facility, 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 commissions and offering costs of \$526	12,604	2	293,288	—	—	293,290
Issuance of common stock through ATM Facility, 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

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

	Year Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	\$ (230,699)	\$ (119,491)	\$ (79,049)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	33,817	23,100	16,784
(Accretion) amortization of investment (discounts) premiums	(1,885)	732	2,582
Depreciation and amortization expense	3,732	956	383
Non-cash interest expense	211	—	—
Asset retirement obligation accretion expense	49	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(5,764)	(784)	(742)
Other assets	(314)	2	6
Accounts payable	(1,958)	2,163	981
Accrued compensation	4,972	1,919	1,121
Accrued research and development expenses	15,204	1,598	(2,704)
Other current liabilities	2,491	1,896	215
Long-term liabilities	372	407	398
Net cash used in operating activities	(179,772)	(87,502)	(60,025)
Investing activities			
Purchases of short-term investments	(466,489)	(176,459)	(304,928)
Sales of short-term investments	109,808	107,627	242,643
Maturities of short-term investments	196,317	188,973	149,046
Purchases of property and equipment	(35,925)	(20,232)	(3,020)
Net cash (used in) provided by investing activities	(196,289)	99,909	83,741
Financing activities			
Proceeds from sale of common stock in underwritten offerings, net	293,290	—	—
Proceeds from issuance of common stock from ATM Facility, net	47,586	19,156	—
Taxes paid related to net share settlement of restricted stock units	(7,503)	(357)	(94)
Proceeds from employee stock awards	24,691	1,249	600
Principal payments on capital lease obligations	(528)	—	—
Net cash provided by financing activities	357,536	20,048	506
(Decrease) increase in cash, cash equivalents and restricted cash	(18,525)	32,455	24,222
Cash, cash equivalents and restricted cash at beginning of period	80,617	48,162	23,940
Cash, cash equivalents and restricted cash at end of period	\$ 62,092	\$ 80,617	\$ 48,162
Non-cash investing and financing activities			
Property and equipment purchases included in accounts payable and other accrued liabilities	\$ 1,579	\$ 10,122	\$ 352
Facility lease financing 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 not yet received	\$ —	\$ 439	\$ —
Accrued costs related to underwritten public offering	\$ —	\$ 160	\$ —
Issuance of common stock upon vesting of stock awards	\$ —	\$ —	\$ 60
Change in long-term liabilities related to non-vested stock awards	\$ —	\$ —	\$ (60)
Supplemental cash flow disclosure			
Cash paid for interest	\$ 240	\$ —	\$ —
Cash paid for taxes	\$ —	\$ —	\$ 10

ATARA BIOTHERAPEUTICS, INC.
Notes to Consolidated Financial Statements

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, or CAR T, program.

We licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center (“MSK”) in June 2015 and licensed rights related to our next-generation CAR T programs from MSK in May 2018 and December 2018 and from Moffitt Cancer Center in August 2018. Additionally, we licensed rights to know-how and technology from the Council of the Queensland Institute of Medical Research (“QIMR Berghofer”) in October 2015, September 2016 and June 2018. See Note 6 for further information.

In January and March 2018, we completed two underwritten public offering of shares of our common stock and received net proceeds of \$293.3 million. Also, in 2018, we received net proceeds of \$47.6 million from the sale of shares of our common stock through our ATM Facility (see Note 8).

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“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 its wholly owned subsidiaries, Atara Biotherapeutics Ireland Limited, an Irish company, Atara Biotherapeutics Switzerland GmbH, a Swiss company and Atara Biotherapeutics Australia Pty. Ltd., an Australian company, and before they were merged into Atara and eliminated in December 2018, Nina Biotherapeutics, Inc., a Delaware corporation, Santa Maria Biotherapeutics, Inc., a Delaware corporation, Pinta Biotherapeutics, Inc., a Delaware corporation and Atara Biotherapeutics Cayman Limited, a Cayman Islands company. All intercompany balances and transactions have been eliminated in consolidation.

Segment and Geographic Information

We operate and manage our business as one reporting and one operating 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, 2018, we had an accumulated deficit of \$527.3 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. Management expects that our cash, cash equivalents and short-term investments as of December 31, 2018 will be sufficient to fund our planned operations to mid-2020.

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 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, stock-based compensation expense, and income taxes. Actual results could differ materially from those estimates.

Leases

We lease office space in multiple locations. In addition, we recently constructed a manufacturing facility in Thousand Oaks, California under a non-cancelable lease agreement. The leases are reviewed for classification as operating, capital or build-to-suit leases. For operating leases, rent is recognized on a straight-line basis over the lease period. For capital leases, we record the leased asset with a corresponding liability for principal and interest. Payments are 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 are the deemed “owner” of the construction project during the construction period. As a result, we are 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 is complete, the Company considers 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. If the arrangement does not qualify for sale-leaseback accounting treatment, the building asset remains on the Company’s consolidated balance sheets at its historical cost, and such asset is depreciated over its estimated useful life. The Company bifurcates 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 is treated for accounting purposes as operating lease payments, and therefore is recorded as rent expense in the consolidated statements of operations and comprehensive loss. The portion of the lease payments allocated to the building is 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 are classified as non-cash investing and financing items, respectively, for purposes of the consolidated statements of cash flows.

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, 2018 were not material. We held no foreign currency as of December 31, 2017.

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 statements of operations 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, 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:

- Level 1: Quoted prices in active markets for identical assets or liabilities that we have the ability to access
- Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data such as quoted prices, interest rates and yield curves
- Level 3: Inputs that are unobservable data points that are not corroborated by market data

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

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

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

Property and Equipment, net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, ranging 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. Equipment leased under capital leases is amortized over the shorter of the lease term or the asset's estimated useful life. 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 for employee awards and the date when the service performance is completed for non-employees. 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 employees' 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 non-employees' awards with performance-based vesting criteria, we assess all possible outcomes at the end of each reporting period and recognize the lowest aggregate fair value in the range of possible outcomes. The lowest value in the range of possible outcomes may be zero. 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 non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date.

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 studies 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.

Other Current Liabilities

As of December 31, 2018, other current liabilities included \$5.6 million of accrued operating expenses, \$0.6 million of current portion of finance and capital lease obligations and \$0.2 million of other accrued liabilities. As of December 31, 2017, other current liabilities included \$2.6 million of accrued operating expenses, \$0.5 million of current portion of capital lease obligations and \$0.2 million of other accrued liabilities.

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, 2018 and 2017. 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 Loss

Comprehensive 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 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 loss to net loss during any period presented.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)*, which is intended to increase the transparency and comparability in the reporting of leasing arrangements by generally requiring leased assets and liabilities to be recorded on the balance sheet. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018.

In July 2018, the FASB issued ASU No. 2018-10, “Codification Improvements to Topic 842, Leases” to clarify the implementation guidance and ASU No. 2018-11, “Leases (Topic 842) Targeted Improvements.” This updated guidance provides an 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. The Company will adopt the new standard on January 1, 2019 and intends to elect certain practical expedients, including the optional transition method that allows for the application of the new standard at its adoption date with no restatement of prior period amounts. We estimate an increase of approximately \$14.3 million for the right of use lease assets, net of adjustments for deferred and prepaid rent, and \$15.3 million for right of use lease liabilities associated with our operating leases upon adoption. This will be partially offset by de-recognition of the build to suit asset and corresponding lease obligation of approximately \$10.3 million for our Thousand Oaks manufacturing facility lease as we did not control the building during the construction period. The cumulative effect adjustment to the opening balance of accumulated deficit is expected to be a decrease of \$0.4 million. The actual impact may differ from our estimate. We believe the adoption of this guidance will not have a significant impact on our consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective for us on January 1, 2020, with early adoption permitted on January 1, 2019. We have not yet determined the potential effect the new standard will have on our consolidated financial statements.

In February 2018, the FASB issued 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 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2018. The new standard is not expected to 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 clarifies the accounting for implementation costs in cloud computing arrangements. The new standard is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2019, with early adoption permitted. We have not yet determined the potential effect the new standard will have on our consolidated financial statements.

Adoption of New Accounting Pronouncements

On January 1, 2018, the Company adopted two new accounting standards issued by the FASB that clarify presentation and classification in the statement of cash flows on a retrospective basis. As a result of adoption, amounts of restricted cash and restricted cash equivalents are now presented with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. As a result of adoption, cash, cash equivalents and restricted cash reported on the consolidated statements of cash flows now includes restricted cash of \$1.4 million, \$0.2 million and \$0.2 million as of December 31, 2017, December 31, 2016 and January 1, 2016, respectively, as well as previously reported cash and cash equivalents.

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 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 and common share equivalents outstanding for the period. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive.

Potentially dilutive securities, which include unvested 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,		
	2018	2017	2016
Unvested RSUs	1,405,460	1,685,000	1,286,262
Vested and unvested options	6,276,999	5,229,648	3,733,847
ESPP share purchase rights	7,974	14,905	7,037
Total	<u>7,690,433</u>	<u>6,929,553</u>	<u>5,027,146</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, 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>

As of December 31, 2017:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
(in thousands)					
Money market funds	Level 1	\$ 68,730	\$ —	\$ —	\$ 68,730
U.S. Treasury obligations	Level 2	39,068	—	(28)	39,040
Government agency obligations	Level 2	4,749	—	(21)	4,728
Corporate debt obligations	Level 2	46,532	2	(98)	46,436
Commercial paper	Level 2	1,592	—	—	1,592
Asset-backed securities	Level 2	4,122	—	(6)	4,116
Total available-for-sale securities		164,793	2	(153)	164,642
Less amounts classified as cash equivalents		(77,769)	—	—	(77,769)
Amounts classified as short-term investments		<u>\$ 87,024</u>	<u>\$ 2</u>	<u>\$ (153)</u>	<u>\$ 86,873</u>

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

	As of December 31, 2018		As of December 31, 2017	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
(in thousands)				
Maturing within one year	\$ 287,755	\$ 287,469	\$ 151,938	\$ 151,852
Maturing in one to five years	23,169	23,115	12,855	12,790
Total available-for-sale securities	<u>\$ 310,924</u>	<u>\$ 310,584</u>	<u>\$ 164,793</u>	<u>\$ 164,642</u>

As of December 31, 2018, 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, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. During the years ended December 31, 2018, 2017 and 2016, 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, 2018 and 2017, restricted cash totaled \$1.4 million and \$1.4 million, respectively.

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, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	\$ 60,698	\$ 79,223
Restricted cash - short-term	194	194
Restricted cash - long-term	1,200	1,200
Total cash, cash equivalents and restricted cash	<u>\$ 62,092</u>	<u>\$ 80,617</u>

5. Property and Equipment

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

	December 31, 2018	December 31, 2017
	(in thousands)	
Leasehold improvements	\$ 47,609	\$ 623
Build-to-suit asset (see Note 7)	10,686	—
Construction in progress	4,682	40,797
Computer equipment and software	3,049	477
Lab equipment	3,019	2,156
Machinery and equipment	2,980	885
Furniture and fixtures	1,628	536
Property and equipment, gross	73,653	45,474
Less accumulated depreciation and amortization	(5,077)	(1,345)
Property and equipment, net	<u>\$ 68,576</u>	<u>\$ 44,129</u>

Construction in progress represents capitalized costs for our manufacturing facility in Thousand Oaks, California. Depreciation and amortization expense was \$3.7 million, \$1.0 million and \$0.4 million for the years ended December 31, 2018, 2017 and 2016, 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 December 2018, we licensed additional technology from MSK. In connection with the effectiveness of this 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 obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional T-cell programs as well as the option to license additional technology 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. The amended and restated license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any.

Under the terms of the amended and restated 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 next-generation CAR T programs from MSK in May 2018 and from Moffitt Cancer Center in August 2018, and 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, 2018 and 2017, there were no outstanding obligations for milestones and royalties under our license and collaboration agreements.

Cognate Agreement – In August 2015, Atara entered into a Development and Manufacturing Services Agreement (the “Manufacturing Agreement”) with Cognate Bioservices, Inc. (“Cognate”). The Manufacturing Agreement was amended in December 2017 to provide for additional rights for Atara in relation to the conduct of the services and amended again in May 2018 to modify certain financial provisions with respect to manufacturing services. Pursuant to the Manufacturing Agreement, Cognate provides process development and manufacturing services for certain Atara product candidates.

7. 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 studies, with contract manufacturing organizations for clinical supplies, and with other vendors for pre-clinical studies, clinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination on notice. As of December 31, 2018 and 2017, there were no amounts accrued related to termination charges for minimum purchase volumes not being met.

Operating, Finance and Capital Leases

Operating 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. We also lease office space in Westlake Village, California under a lease agreement that expires in April 2019. In November 2018, we entered into a lease agreement for additional office space in Thousand Oaks, California that expires in February 2026.

Finance Leases

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 due to our involvement in certain aspects of the construction, we were deemed the owner of the building (for accounting purposes only) during the construction period in accordance with U.S. GAAP. 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.

As of December 31, 2018, 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 have 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 is 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 is applied to the lease financing liability. Further, we recorded ground lease expense of \$0.4 million 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. Ground lease expense for the year ended December 31, 2016 was zero.

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

	Operating Leases	Finance Leases	Capital Leases
Years Ending December 31,	(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	—
Total minimum payments	<u>\$ 10,162</u>	<u>\$ 16,416</u>	<u>\$ 803</u>
Less: amount representing interest			65
Present value of capital lease obligations			738
Less: current portion			490
Capital lease obligation, net of current portion			<u>\$ 248</u>

Rent expense under operating leases for the years ended December 31, 2018, 2017 and 2016 was \$2.2 million, \$1.4 million and \$1.2 million, respectively.

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 as construction in progress. 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, 2017	\$	580
Liabilities incurred during the year		88
Accretion expense		49
Balance as of December 31, 2018	\$	717

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, 2018 and 2017.

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.

8. 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, 2018 and 2017.

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.

ATM Facilities

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

During the fiscal years ended December 31, 2018 and December 31, 2017, we sold an aggregate of 1,007,806 and 1,349,865 shares of common stock, respectively, under the ATM Facility, at an average price of approximately \$48.52 and \$14.82 per share, respectively, for gross proceeds of \$48.9 million \$20.0 million, respectively, and net proceeds of \$47.6 million and \$19.2 million, respectively, after deducting commissions and other offering expenses. The issuance and sale of these shares by us pursuant to the ATM Facility are deemed an “at-the-market” offering and were registered under the Securities Act of 1933, as amended. As of December 31, 2018, we had approximately \$6.1 million of common stock remaining to be sold under the ATM Facility.

In February 2019, we terminated the ATM Facility and entered into a new sales agreement (the “New 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 issuance and sale of these shares by us pursuant to the New 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 New ATM Facility.

Equity Incentive Plan

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 typically require settlement by the earlier of seven years from the date of grant or the service termination (or, for RSUs granted prior to February 2014, two years following the service termination date). 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 to employees and non-employees generally vest over four years and expire in seven years. As of December 31, 2018, a total of 10,306,803 shares of common stock were reserved for issuance under the 2014 EIP, of which 3,265,910 shares were available for future grant and 7,040,893 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, 2018, 1,250,000 shares of common stock were reserved for issuance under the Inducement Plan, of which 720,000 shares were available for future grant and 530,000 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, 2018, 2017 and 2016 was \$36.83, \$15.07 and \$17.83, respectively. As of December 31, 2018, there was \$29.3 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.5 years. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2018 was \$48.9 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, 2017	1,685,000	\$ 16.90
Granted	836,487	\$ 36.83
Forfeited	(492,894)	\$ 21.51
Vested	(623,133)	\$ 17.37
Unvested as of December 31, 2018	1,405,460	\$ 26.94
Vested and unreleased	2,100	
Outstanding as of December 31, 2018	1,407,560	

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 2018, we settled 638,518 RSUs, of which 440,503 RSUs were net settled by withholding 190,205 shares. The value of the RSUs withheld was \$7.5 million, based on the closing price of our common stock on the settlement date. During 2017, we settled 327,282 RSUs, of which 52,624 RSUs were net settled by withholding 22,274 shares. The value of the RSUs withheld was \$0.4 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, 2017	5,229,648	\$ 21.06		
Granted	2,998,650	38.69		
Exercised	(1,051,180)	21.57		
Forfeited or expired	(900,119)	29.77		
Outstanding as of December 31, 2018	<u>6,276,999</u>	\$ 28.15	5.3	\$ 54,831
Vested and expected to vest as of December 31, 2018	6,276,999	\$ 28.15	5.3	\$ 54,831
Exercisable as of December 31, 2018	2,281,931	\$ 21.44	4.1	\$ 31,212

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2018 and the exercise price of outstanding, in-the-money options. As of December 31, 2018, there was \$67.8 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.9 years.

Options for 1,051,180, 60,125 and 18,947 shares of our common stock were exercised during the years ended December 31, 2018, 2017 and 2016, with an intrinsic value of \$19.2 million, \$0.2 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,		
	2018	2017	2016
Assumptions:			
Expected term (years)	4.6	4.5	4.5
Expected volatility	73.5 %	71.3 %	69.0 %
Risk-free interest rate	2.7 %	1.9 %	1.3 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Fair Value:			
Weighted-average estimated grant date fair value per share	\$ 22.96	\$ 9.01	\$ 11.02
Options granted	2,998,650	1,694,000	966,250
Total estimated grant date fair value	<u>\$ 68,849,000</u>	<u>\$ 15,263,000</u>	<u>\$ 10,648,000</u>

The estimated fair value of stock options that vested in the years ended December 31, 2018, 2017 and 2016 was \$16.2 million, \$14.0 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 be issued or transferred 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 \$1.2 million, \$0.6 million and \$0.4 million of expense related to the 2014 ESPP in the years ended December 31, 2018, 2017 and 2016, respectively. A total of 109,193, 81,922 and 22,844 shares were purchased under the ESPP during the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, there was \$0.4 million of unrecognized stock-based compensation expense related to the ESPP that is expected to be recognized by the end of second quarter of 2019.

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, 2018, there were 911,245 shares available for purchase under the 2014 ESPP.

Reserved Shares

The following shares of common stock were reserved for future issuance as of December 31, 2018:

	Total Shares Reserved
2014 Equity Incentive Plan	10,306,803
2018 Inducement Plan	1,250,000
2014 Employee Stock Purchase Plan	911,245
Options granted outside the equity plans	113,666
Total reserved shares of common stock	<u>12,581,714</u>

Stock-based Compensation Expense

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

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Research and development	\$ 16,211	\$ 8,778	\$ 7,612
General and administrative	17,606	14,322	9,172
Total stock-based compensation expense	<u>\$ 33,817</u>	<u>\$ 23,100</u>	<u>\$ 16,784</u>

9. Income Taxes

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

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
United States	\$ (230,765)	\$ (12,894)	\$ (48,795)
Foreign	22	(106,611)	(30,244)
Total loss before income taxes	<u>\$ (230,743)</u>	<u>\$ (119,505)</u>	<u>\$ (79,039)</u>

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 income tax provision (benefit) were as follows in each period presented:

	Year Ended December 31,		
	2018	2017	2016
Current (benefit from) provision for income taxes:	(in thousands)		
Federal	\$ (31)	\$ (14)	\$ —
State	(15)	—	10
Foreign	2	—	—
Total current (benefit from) provision for income taxes	<u>\$ (44)</u>	<u>\$ (14)</u>	<u>\$ 10</u>

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

	Year Ended December 31,		
	2018	2017	2016
Federal income taxes at statutory rate	21.0 %	34.0 %	34.0 %
Impact of stock compensation	—	(1.5 %)	(1.3 %)
Foreign income tax at different rate	—	(30.3 %)	(13.0 %)
Impact of U.S. tax reform	—	(11.3 %)	—
Non-deductible executive compensation	(0.7 %)	—	—
Capitalized research	7.8 %	—	—
Other	(0.6 %)	(3.8 %)	(0.9 %)
Change in valuation allowance	(27.5 %)	12.9 %	(18.8 %)
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 as of the dates indicated:

	As of December 31,	
	2018	2017
Deferred tax assets:	(in thousands)	
Net operating losses	\$ 91,994	\$ 31,110
License fees	7,380	2,940
Stock-based compensation	8,578	10,489
Capitalized expenses	16,019	—
Legal fees	1,375	1,490
Other	1,807	1,268
Total deferred tax assets	127,153	47,297
Valuation allowance	(127,153)	(47,297)
Net deferred tax assets	<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, 2018 and 2017. 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 \$79.9 million for the year ended December 31, 2018 and decreased by \$8.6 million for the year ended December 31, 2017.

As of December 31, 2018, we had federal and state net operating loss carryforwards for tax return purposes of \$293.9 million and \$449.8 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2032 in various amounts if not utilized. Of the \$293.9 million federal net operating losses, \$216.8 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 (the “Code”), 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, 2018. 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.

In 2018, the measurement period to adjust provisional amount recorded under SAB 118 closed. The Company did not record significant adjustments to provisional amounts that were recorded in 2017.

The changes in the balance of gross unrecognized tax benefits, which excludes interest and penalties, for the years ended December 31, 2016, 2017 and 2018 are as follows:

	(In thousands)
Balance as of January 1, 2016	\$ 4,314
Gross increases for tax positions related to current year	4,971
Balance as of December 31, 2016	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

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 \$41.1 million total unrecognized tax benefits as of December 31, 2018, 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, 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) of the Exchange Act as of December 31, 2018). 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, 2018 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, 2018 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, 2018. The effectiveness of our internal control over financial reporting as of December 31, 2018 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, 2018, 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, 2018 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, 2018, 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, 2018, 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, 2018, of the Company and our report dated February 26, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying “Management’s Report on Internal Control over Financial Reporting”. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ DELOITTE & TOUCHE LLP

San Jose, California
February 26, 2019

Item 9B. Other Information

On February 26, 2019, we entered into a sales agreement, or the New 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. In connection with the entry into the New ATM Facility, we terminated our prior sales agreement, dated March 27, 2017, with Cowen.

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 New ATM Facility, and also have provided Cowen with customary indemnification rights.

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

The foregoing description of the New ATM Facility is qualified in its entirety by reference to the New 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 New ATM Facility is filed as Exhibit 5.1 to this Annual Report on Form 10-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 2019 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, 2018, 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. 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	Sales Agreement, dated February 26, 2019, by and between Atara Biotherapeutics, Inc. and Cowen and Company, LLC					X
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	06/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	06/20/2014	
4.1	Form of Common Stock Certificate	S-1/A	333-196936	4.1	07/10/2014	
4.2	Investors' Rights Agreement, by and among Atara Biotherapeutics, Inc. and the stockholders named therein, dated March 31, 2014	S-1	333-196936	4.2	06/20/2014	
5.1	Opinion of Cooley LLP					X
10.1*	Amended and Restated 2014 Equity Incentive Plan	10-Q	001-36548	10.2	08/08/2016	
10.2*	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan	S-1	333-196936	10.2	06/20/2014	
10.3*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2014 Equity Incentive Plan	S-1	333-196936	10.3	06/20/2014	
10.4*	2014 Employee Stock Purchase Plan	S-1/A	333-196936	10.8	07/10/2014	
10.5*	Atara Biotherapeutics, Inc. 2018 Inducement Plan (the "Inducement Plan")	10-Q	001-36548	10.1	05/08/2018	
10.6*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the Inducement Plan	10-Q	001-36548	10.2	05/08/2018	
10.7*	Form of Stock Option Agreement and Stock Option Grant Notice under the Inducement Plan	10-Q	001-36548	10.3	05/08/2018	
10.8*	Forms of Inducement Grant Notice and Inducement Grant Agreement	10-Q	001-36548	10.3	08/07/2017	
10.9*	Form of Indemnification Agreement made by and between Atara Biotherapeutics, Inc. and each of its directors and executive officers	S-1	333-196936	10.9	06/20/2014	
10.10*	Form of Employment Agreement by and between Atara Biotherapeutics, Inc. and its executive officers.	10-Q	001-36548	10.4	08/01/2018	
10.11*	Amended and Restated Executive Employment Agreement by and between Atara Biotherapeutics, Inc. and Isaac E. Ciechanover, dated October 12, 2015	8-K	001-36548	10.1	10/16/2015	
10.12*	Transition and Separation Agreement, dated January 2, 2019, by and between Isaac Ciechanover and Atara Biotherapeutics, Inc.	8-K	001-36548	10.1	01/03/2019	
10.13†	Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015	S-1	333-205347	10.30	06/29/2015	
10.14†	Amendment No. 1 to the Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of August 30, 2018					X
10.15†	Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Council of the Queensland Institute of Medical Research, dated September 23, 2016, as amended	10-Q	001-36548	10.01	08/01/2018	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.16†	Amended and Restated Research and Development Collaboration Agreement, by and between Atara Biotherapeutics, Inc. and the Council of the Queensland Institute of Medical Research, dated September 2016, as amended	10-Q	001-36548	10.02	08/01/2018	
10.17†	Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate Bioservices, Inc., dated August 2015, as amended	10-Q	001-36548	10.03	08/01/2018	
10.18	Office Lease, by and between Atara Biotherapeutics, Inc. and BPG Rock Westlake, LLC, dated January 7, 2015	10-Q	001-36548	10.33	11/06/2015	
10.19	First Amendment to Lease, by and between BPG Rock Westlake, LLC and Atara Biotherapeutics, Inc., dated as of September 9, 2015	10-Q	001-36548	10.34	11/06/2015	
10.20	Office Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated as of December 9, 2015	10-K	001-36548	10.29	03/04/2016	
10.21	Standard Industrial Lease by and between Thousand Oaks Industrial Portfolio, LLC and Atara Biotherapeutics, Inc. dated February 6, 2017	10-Q	001-36548	10.1	05/04/2017	
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
23.2	Consent of Cooley LLP (included in Exhibit 5.1)					X
24.1	Power of Attorney (included on signature page)					
31.1	Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13A-14A and 15D-14A					X
31.2	Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13A-14A and 15D-14A					X
32.1(1)	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					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

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

* 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 USC. 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.

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 26th day of February, 2019.

Atara Biotherapeutics, Inc.

By: /s/ Isaac E. Ciechanover

Isaac E. Ciechanover, M.D.

President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Isaac E. Ciechanover 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Isaac E. Ciechanover</u> Isaac E. Ciechanover, M.D.	President and Chief Executive Officer <i>(principal executive officer)</i>	February 26, 2019
<u>/s/ Utpal Koppikar</u> Utpal Koppikar	Chief Financial Officer <i>(principal financial and accounting officer)</i>	February 26, 2019
<u>/s/ Roy D. Baynes</u> Roy D. Baynes, M.D., Ph.D.	Director	February 26, 2019
<u>/s/ Eric Dobmeier</u> Eric Dobmeier	Director	February 26, 2019
<u>/s/ Matthew K. Fust</u> Matthew K. Fust	Director	February 26, 2019
<u>/s/ Carol G. Gallagher</u> Carol G. Gallagher, Pharm.D.	Director	February 26, 2019
<u>/s/ William Heiden</u> William Heiden	Director	February 26, 2019
<u>/s/ Joel S. Marcus</u> Joel S. Marcus	Director	February 26, 2019
<u>/s/ Beth Seidenberg</u> Beth Seidenberg, M.D.	Director	February 26, 2019

ATARA BIOTHERAPEUTICS, INC.

\$100,000,000

COMMON STOCK

SALES AGREEMENT

February 26, 2019

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 and declared effective by 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 or 462(b) 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 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 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 (2nd) 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 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 and any Rule 462(b) Registration Statement have been declared effective by 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 or any Rule 462(b) 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. 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.

(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 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, 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 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 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.

(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 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 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 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 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 an y 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. 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 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 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 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.

(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 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 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, 27th 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, 5th Floor, San Francisco, California 94111; fax no. 415-693-2222, attention: Jodie Bourdet. 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 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.

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: the seventh and eighth paragraphs under the caption “Plan of Distribution” in the Prospectus.

21. Termination of Prior Agreement. Reference is hereby made to that certain Sales Agreement dated March 27, 2017 between the Company and Cowen (the “Prior Agreement”). Cowen and the Company (a) agree that, concurrently with the effectiveness of this Agreement on the date hereof, the Prior Agreement shall automatically terminate, without any further action by the parties thereto, but subject, however, to Section 11(e) of the Prior Agreement, which provides that certain terms and provisions of the Prior Agreement shall survive such termination and remain in full force and effect and (b) waive any advance notice required by Section 11 of the Prior Agreement with respect to such termination.

[Remainder of Page Intentionally Blank]

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

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 26, 2019 (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 \$[]].

The Company:

- Isaac Ciechanover
- Utpal Koppikar
- Mina Kim

The Agent:

- Mike Murphy
 - Bill Follis
-

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.

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 26, 2019 (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: _____

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

February 26, 2019

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 26, 2019 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 26, 2019, 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. 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. 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; and the accuracy, completeness and authenticity of certificates of public officials.

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 3,125,000 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 26, 2019
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

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

AMENDMENT NO. 1 TO THE EXCLUSIVE LICENSE AGREEMENT

This Amendment No. 1 to the Exclusive License Agreement (this “**Amendment**”) is made and entered into, effective as of August 30, 2018 (“**Amendment Effective Date**”), by and between **Memorial Sloan Kettering Cancer Center** (“**MSK**”), a New York not-for-profit corporation with principal offices at 1275 York Avenue, New York, NY 10065, and **Atara Biotherapeutics, Inc.** (“**Licensee**”), a corporation with offices at 611 Gateway Blvd, Suite 900, South San Francisco, CA 94080. MSK and Licensee are sometimes referred to singly as “**Party**” and collectively as “**Parties**.”

Background

WHEREAS, the Parties have entered into that certain Exclusive License Agreement (the “**Agreement**”) effective as of June 12, 2015 (the “**Effective Date**”), pursuant to which MSK has granted to Licensee an exclusive license under certain patents and know how owned or controlled by MSK to develop and commercialize T-cell products specific to CMV, EBV or WT1;

WHEREAS, MSK owns certain additional patents and know-how useful for the discovery and development of such T-cell products for use in the treatment of human disease, and desires to have such patents and know-how utilized in the public interest;

WHEREAS, the Parties desire to amend the Agreement to include such additional patents and know-how under the license granted by MSK to Licensee to develop and commercialize such T-cell products, among other changes set forth in this Amendment; and

WHEREAS, Section 19.7 of the Agreement provides that the Agreement may only be modified by a writing signed by each Party to the Agreement.

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

ARTICLE 1 DEFINITIONS

1.1 Capitalized Terms. Capitalized terms used in this Amendment shall have the meanings set forth in the Agreement unless otherwise defined and set forth in this Amendment. Except as expressly modified by this Amendment, the remainder of the Agreement shall remain in force in accordance with its terms and without any modification.

ARTICLE 2
AMENDMENTS

2.1 Amendment of Section 1.16. Section 1.16 of the Agreement is hereby amended and restated in its entirety as follows:

1.16 “**Licensed Know-How**” means all know-how, inventions (whether or not patentable), data, results, protocols, regulatory filings, assays and other information (including the PD1-DNR Know-How) relating to or useful for making, propagating, improving, maintaining and/or using the Licensed products and/or the Library, that are owned or controlled by MSK at any time during the Term of this Agreement, including the Databases, and including the information generally described in the application section of Exhibit A of this Agreement.

2.2 Amendment of Section 1.18. Section 1.18 of the Agreement is hereby amended and restated in its entirety as follows:

1.18 “**Licensed Product**” means:

(a) (i) any T-cell product specific to CMV, EBV, or WT1 made, used, imported, offered for sale, sold, reproduced, performed, displayed, distributed, or otherwise utilized by or on behalf of Licensee, or its sublicensees, that comprises, is based on or is made using Licensed Rights, including any such product that is an EBV Product, CMV Product, WT1 Product and/or Follow-On Product, and (ii) is not an Excluded Product; or

(b) a PD1-DNR Product.

2.3 Addition of New Section 1.34. Article 1 of the Agreement is hereby amended by adding a new Section 1.34 thereto as follows

1.34 “**EMA**” means the European Medicines Agency or any successor entity thereto.

2.4 Addition of New Section 1.35. Article 1 of the Agreement is hereby amended by adding a new Section 1.35 thereto as follows:

1.35 “**FDA**” means the U.S. Food and Drug Administration or any successor entity.

2.5 Addition of New Section 1.36. Article 1 of the Agreement is hereby amended by adding a new Section 1.36 thereto as follows:

1.36 “**Initiation**” means, with respect to a clinical study, the first dosing of the first human subject in such clinical study.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

2.6 Addition of New Section 1.37. Article 1 of the Agreement is hereby amended by adding a new Section 1.37 thereto as follows:

1.37 “**PD1-DNR Know-How**” means the know-how, inventions (whether or not patentable, data, results, protocols, regulatory filings, assays and other information that is (a) owned or controlled by MSK as of the Effective Date or during the Term of this Agreement, and (b) necessary for the practice of the inventions claimed in the PD1-DNR Patent Rights, that is set forth on Exhibit A.

2.7 Addition of New Section 1.38. Article 1 of the Agreement is hereby amended by adding a new Section 1.38 thereto as follows:

1.38 “**PD1-DNR Patent Rights**” means:

- (a) The patents and applications listed on Exhibit C(ii) of this Agreement (including any patent applications added to Exhibit C(ii) pursuant to Section 7.1);
- (b) U.S. and ex-U.S. patents that issue from or claim priority to any applications in (a), but not including claims in continuation-in-part applications or patents except to the extent provided in (c) below;
- (c) Claims in continuation-in-part applications or patents described in (b) above to the extent that such claims are entitled to priority to patents or patent applications in (a);
- (d) Any reissues or re-examinations of patents described in (a), (b), or (c) above; and
- (e) Any ex-US applications and patents that are equivalent to any of the foregoing.

2.8 Addition of New Section 1.39. Article 1 of the Agreement is hereby amended by adding a new Section 1.39 thereto as follows:

1.39 “**PD1-DNR Product**” means any [*] made, used, imported, offered for sale, sold, reproduced, performed, displayed, distributed, or otherwise utilized by or on behalf of Licensee, or its sublicensees, that comprises, is based on or is made using PD1-DNR Patent Rights or the PD1-DNR Know-How, including any such product that is [*].

2.9 Addition of New Section 1.40. Article 1 of the Agreement is hereby amended by adding a new Section 1.40 thereto as follows:

1.40 “**Phase 1 Study**” means that portion of the drug development and review process which provides for the initial introduction of an investigational new drug into humans in any country that would satisfy the requirements of 21 C.F.R 312.21(a) (FDCA), as amended from time to time, and the ex-US national equivalent thereof.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

2.10 Addition of New Section 1.41. Article 1 of the Agreement is hereby amended by adding a new Section 1.41 thereto as follows :

1.41 “**Pivotal Clinical Trial**” means a human clinical trial of a product on a sufficient number of subjects that, prior to commencement of the trial, satisfies both of the following ((a) and (b)):

- (a) such trial is designed to establish that such product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such product, or a similar clinical study prescribed by the FDA or EMA; and
- (b) such trial is a registration trial sufficient for filing an application for a Regulatory Approval for such product in the U.S. or another country or some or all of an extra-national territory, as evidenced by (i) an agreement with or statement from the FDA or the EMA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA or EMA, for such registration trial.

2.11 Addition of New Section 1.42. Article 1 of the Agreement is hereby amended by adding a new Section 1.42 thereto as follows:

1.42 “**Regulatory Approval**” means, with respect to a country in the Territory, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations and (c) labeling approval.

2.12 Addition of New Section 1.43. Article 1 of the Agreement is hereby amended by adding a new Section 1.43 thereto as follows:

1.43 “**Regulatory Authority**” means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Licensed Products in the Territory, including the FDA and the EMA.

2.13 Addition of New Section 1.44. Article 1 of the Agreement is hereby amended by adding a new Section 1.44 thereto as follows:

1.44 “**Special Protocol Assessment**” means the procedures adopted by the United States Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research for evaluating issues related to the adequacy of certain proposed studies associated with the development of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) for products covered by the Prescription Drug User Fee Act of 1992, as further described in section 119(a) of the Food and Drug Administration Modernization Act.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

2.14 Amendment of Section 5.1(d). Section 5.1(d) of the Agreement is hereby amended and restated in its entirety as follows:

(d) Milestones:

Milestone payments as follows:

(i) The following milestone payments shall be due for a Licensed Product (other than a PD1-DNR Product) for the first indication only. For clarity, one set of milestone payments will be payable for a Licensed Product that is an EBV Product, a second set of milestone payments will be payable for a Licensed Product that is a CMV Product, and a third set of milestones payments will be payable for a Licensed Product that is a WT1 Product:

(A) [*]

(B) [*]

(C) [*]

For clarity, each above milestone payment shall be made only once with respect to any Licensed Product that is an EBV Product, once with respect to any Licensed Product that is a CMV Product, and once with respect to any Licensed Product that is a WT1 Product.

(ii) The following milestone payments shall be due for a PD1-DNR Product for the first indication only. For clarity, one set of milestone payments will be payable for a PD1-DNR Product that [*], a second set of milestone payments will be payable for a PD1-DNR Product that [*], and a third set of milestones payments will be payable for a PD1-DNR Product that [*]:

(A) [*]

(B) [*]

(C) [*]

(D) [*]

(E) [*]

(F) [*]

(G) [*]

(H) [*]

(I) [*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

For clarity, (1) each above milestone payment shall be made only once with respect to any [*], once with respect to any [*], and once with respect to any [*], and (2) in no event will a PD1-DNR Product for which milestones are payable under this Section 5.1(d)(ii) also be considered a Licensed Product for the purposes of Section 5.1(d)(i).

2.15 Addition of new **Section 5.1(f)**. Article 5 of the Agreement is hereby amended by adding a new Section 5.1(f) thereto as follows:

Avoidance of Double Royalties and Milestones . Licensee will not be obligated to pay royalties to MSK on any given PD1-DNR Product under both this Agreement and that certain [*], nor shall Licensee be obligated to make milestone payments for the same milestone event for a given PD1-DNR Product under both this Agreement and the [*]. If a PD1-DNR Product for which a royalty is owed to MSK under this Agreement is also by the terms of the [*] royalty bearing under the [*], Licensee shall be required to pay to MSK the [*] of (i) [*], or (ii) [*]. Upon payment of the [*] (i) or (ii) under the relevant agreement, the corresponding royalty under the other agreement shall be deemed to have been paid. Similarly, if a milestone event triggers a milestone payment under both this Agreement and under the [*], Licensee shall be required to pay MSK the [*] milestone payment, and upon such payment the [*] milestone payment shall be deemed to have been paid.

2.16 Amendment of **Section 7.2**. Section 7.2 of the Agreement is hereby amended and restated in its entirety as follows:

7.2 MSK shall undertake, at Licensee's expense (as provided below) and using Commercially Reasonable Efforts, and as directed by the IP Committee, to prosecute and maintain the Licensed Patent Rights owned solely by MSK in the United States and in such countries as are determined by MSK upon consultation with Licensee, using counsel of MSK's choice reasonably acceptable to Licensee. Licensee shall reimburse MSK for the actual Patent Expenses incurred in such prosecution and maintenance of the Licensed Patent Rights, pursuant to invoices showing the actual Patent Expenses incurred which shall include copies of the documentation demonstrating the out-of-pocket expenses. If Licensee advises that it does not wish to pursue or maintain a patent or application, MSK may continue to prosecute and maintain it at its own expense, and such patent or application shall be excluded from the license granted hereunder if MSK does so. However, the same item of Patent Expenses that is reimbursable under more than one of (a) this Agreement, (b) [*], and (c) the [*] Agreement, as amended, shall be reimbursed by Atara to MSK under only one of the agreements, as follows: (i) reimbursement of applicable Patent Expenses will first be made under the [*] Agreement if applicable, (ii) if not reimbursed under the foregoing (a), under the [*] Agreement, if applicable, and (iii) if not reimbursed under the foregoing (a) or (b), under this Agreement, if applicable, unless Licensee advises that it does not wish to pursue or maintain such patent or application under this Agreement, in which case MSK may continue to prosecute and maintain it at its own expense, and such patent or application shall be excluded from the license granted hereunder.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

2.17 Amendment of Exhibit A. Exhibit A of the Agreement is hereby amended and restated in its entirety in the form attached to this Amendment.

2.18 Amendment of Exhibit C. Exhibit C of the Agreement is hereby amended and restated in its entirety in the form attached to this Amendment.

ARTICLE 3 MISCELLANEOUS

3.1 No Waiver. Nothing in this Amendment is intended to operate as a waiver of any claims either Party may have against the other Party arising prior to the date of this Amendment, including any claims arising prior to the date of this Amendment with respect to the performance of the Parties under the Agreement. Any delay in enforcing a Party's rights under this Amendment or the 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 Amendment or the 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.

3.2 Miscellaneous. This Amendment shall be 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, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was filed or granted. Except as specifically amended by this Amendment, the terms and conditions of the Agreement shall remain in full force and effect. This 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 Agreement, as amended by this Amendment, including all appendices, exhibits and schedules to each of the foregoing, constitute the entire agreement between the Parties relating to the subject matter of the Agreement and supersedes all previous oral and written communications, including all previous agreements, between the Parties.

[Remainder of Page Intentionally Left Blank]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, MSK and Licensee have executed this Amendment by their respective officers hereunto duly authorized, on the day and year hereinafter written. The Parties acknowledge and agree that the signature date may not be the Amendment Effective Date.

MEMORIAL SLOAN KETTERING CANCER CENTER

By: /s/ Gregory Raskin, M.D.
Name: Gregory Raskin, M.D.
Title: Vice President, Technology Development

ATARA BIOTHERAPEUTICS, INC.

By: /s/ Isaac Ciechanover
Name: Isaac Ciechanover
Title: CEO and President

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit A

Licensed Tangible Materials and Licensed Know How

Licensed Tangible Materials.

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Licensed Know-How.

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit C

Licensed Patent Rights

(i)

[*]

(ii) PD1-DNR Patent Rights

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of the Company as of December 31, 2018:

<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 Switzerland GmbH	Switzerland

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statements No. 333-207876 and 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 on Form S-8 of our reports dated February 26, 2019, 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, 2018.

/s/ DELOITTE & TOUCHE LLP

San Jose, California
February 26, 2019

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Isaac Ciechanover, 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 26, 2019

/s/ Isaac Ciechanover

Isaac Ciechanover
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 26, 2019

/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, 2018, as filed with the Securities and Exchange Commission (the "Report"), Isaac Ciechanover, 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 26, 2019

/s/ Isaac Ciechanover

Isaac Ciechanover
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Utpal Koppikar

Utpal Koppikar
Chief Financial Officer
(Principal Financial and Accounting Officer)

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.