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, 2023

OR

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

For the transition period from _____ to

Commission File Number 001-36548

ATARA BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-0920988**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2380 Conejo Spectrum Street, Suite 200	
Thousand Oaks, CA	**91320**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: **(805) 623-4211**

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share,	ATRA	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of common stock held by non-affiliates of the Registrant, based on the closing sales price for such stock on June 30, 2023 as reported by The Nasdaq Stock Market, was $161,602,451. This calculation excludes 727,959 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 March 20, 2024 was 119,359,230.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2024 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 the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements, which represent our intent, belief or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "predict," "plan," "expect" or the negative or plural of these words or similar expressions. The forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the timing of initiating clinical studies, opening client sites, enrolling clinical studies and reporting results of clinical studies for our programs, including our ATA3219 program;
- the likelihood and timing of regulatory submissions or related approvals for our product candidates, including the initiation, completion and expectations about the timing of approvals for a biologics license application (BLA) for tab-cel® for patients with Epstein-Barr virus with post-transplant lymphoproliferative disease (EBV+ PTLD);
- the potential indications for our product and product candidates;
- commercialization of tab-cel (Ebvallo™ in the United Kingdom (UK) and the European Union (EU)) worldwide and our amended and restated Commercialization Agreement with Pierre Fabre Medicament, including potential milestone and royalty payments under the agreement (Ebvallo in the UK and the EU subject to the Purchase and Sale Agreement with HCR Molag Fund, L.P.);
- our Purchase and Sale Agreement and related transactions with HCR Molag Fund, L.P.;
- our Commercial Manufacturing Services Agreement with Charles River Laboratories, Inc. (CRL) and other agreements we may enter into with CRL, including our ability to enter into a new drug supply agreement with CRL on terms favorable or acceptable to us, or at all;
- our Master Services and Supply Agreement and related transactions with FUJIFILM Diosynth Biotechnologies California, Inc.;
- our expectations regarding the potential commercial market opportunities, market size and the size of the patient populations for our product and product candidates;
- 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, including our going concern assessment;
- our ability to enter into favorable commercialization arrangements with third parties to commercialize our product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical studies;
- the initiation, timing, costs, progress and results of future preclinical studies and clinical studies and our research and development programs;
- our ability to enter into and maintain contracts with clinical research organizations, contract manufacturing organizations (CMOs) and other vendors for clinical and preclinical studies, supplies and other services;
- the scope of protection we are able to obtain and maintain for the intellectual property rights covering our product and product candidates;
- our financial performance;
- our election to rely on reduced reporting and disclosure requirements available to smaller reporting companies;
- developments and projections relating to our competitors and our industry;
- our ability to have our product and product candidates manufactured for our clinical studies or for commercial sale, including at commercially reasonable values;
- the impact of public health emergencies, such as COVID-19, to our business and operations, as well as the businesses and operations of third parties on which we rely;

•the impact of our workforce reductions on our ability to attract, retain and motivate qualified personnel and on our business, operations and financial condition; and

•timing and costs related to the qualification of the manufacturing facilities of our CMOs for commercial production.

These statements are only current predictions and are subject to known and unknown risks, uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; the sufficiency of our cash resources and need for additional capital; and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this report in greater detail under the heading "1A. Risk Factors" and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

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

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. These risks are more fully described under the heading "1A. Risk Factors" and elsewhere in this report and include, among others:

•we have incurred substantial losses since our inception and anticipate that we will continue to incur substantial losses for the foreseeable future;

•we have earned limited commercialization revenues to date, and we may never achieve profitability;

•we have one approved product, Ebvallo, in the EU and the UK, are generally early in our development efforts and have only a small number of product candidates in clinical development, and all of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop, manufacture and commercialize our product or product candidates or experience significant delays in doing so, our business may be materially harmed;

•we will require substantial additional financing on terms acceptable to us 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 manufacturing efforts;

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

•the results of preclinical studies or earlier clinical studies are not necessarily predictive of future results, and our existing product candidates in clinical studies, and any other product candidates we advance into clinical studies may not have favorable results in later clinical studies or receive regulatory approval;

•clinical drug development involves a lengthy and expensive process with an uncertain outcome;

•our T-cell immunotherapy product and 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 our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates;

•there can be no assurance that we will achieve all of the anticipated benefits of the Fujifilm Transaction and we could face unanticipated challenges;

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

•we may not be able to obtain or maintain orphan drug exclusivity for our product candidates;

•the proposed revision of the European legislation on pharmaceuticals could lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU, including orphan medicinal products;

•we have been affected by and could be adversely affected in the future by the effects of health epidemics and pandemics, such as the COVID-19 pandemic, which could materially and adversely affect our business and operations in the future, as well as the businesses and operations of third parties on which we rely;

•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;

•our principal stockholders own a significant percentage of our stock and will be able to exert control or significant influence over matters subject to stockholder approval;

•if we fail to continue to meet the listing standards of the Nasdaq Stock Market LLC (Nasdaq), our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock;

•we recently qualified as a "smaller reporting company" and a "non-accelerated filer," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to such companies could make our stock less attractive to investors;

•our workforce reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business; and

•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 or CMOs, development and/or commercialization of our product and product candidates may be adversely affected.

PART I

Item 1. Business

Overview

Atara Biotherapeutics is a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune disease. Tab-cel (tabelecleucel), our lead program in Phase 3 clinical development in the U.S., has received marketing authorization approval (MAA) under the proprietary name Ebvallo™ for commercial sale in the European Union (EU) by the European Commission (EC) and for commercial sale and use in the United Kingdom (UK) by the Medicines and Healthcare products Regulatory Agency (MHRA). We are the most advanced allogeneic T-cell immunotherapy company and intend to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-driven diseases or other serious diseases through incorporation of engineered chimeric antigen receptors (CARs) or T-cell receptors (TCRs). We are applying this one platform, that does not require TCR or human leukocyte antigen (HLA) gene editing, to create a robust pipeline. Our strategic priorities are:

- ***Tab-cel®***: Our most advanced T-cell immunotherapy program, tab-cel, has received MAA for commercial sale in the EU and the UK under the proprietary name Ebvallo and is partnered with Pierre Fabre Medicament (Pierre Fabre) for commercialization in Europe and potential commercialization, if approved, worldwide, including in the U.S. Tab-cel is currently in Phase 3 development in the U.S. for patients with EBV- associated post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-driven diseases; and

- ***ATA3219***: Allogeneic CAR T targeting CD19, currently in Phase 1 development is being developed as a potential best-in-class product intended to target B-cell malignancies and autoimmune diseases, based on a next generation 1XX co-stimulatory domain and the innate advantages of EBV T cells as the foundation for an allogeneic CAR T platform.

In addition to the aforementioned strategic priorities, we also have a number of preclinical programs, including ATA3431, an allogeneic dual CAR T immunotherapy targeting both CD19 and CD20 for B-cell malignancies; and a potential next generation EBV vaccine which is differentiated from earlier EBV vaccine efforts that solely focused on B cell responses to EBV. We have paused development on ATA188, an allogeneic T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS), while we explore strategic options for this asset.

Our T-cell immunotherapy platform is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. We select the appropriate set of cells for use based on a patient's unique immune profile. We estimate that only four and six unique ATA3219 lots will be needed to cover approximately 90% of U.S. NHL and lupus patients, respectively. One of our contract manufacturing organizations (CMOs) has completed commercial production qualification activities for tab-cel and another of our CMOs is currently in the process of completing commercial production qualification activities for tab-cel while we manufacture inventory according to Pierre Fabre's commercial product supply strategy.

In October 2021, we entered into the Commercialization Agreement with Pierre Fabre (Pierre Fabre Commercialization Agreement), pursuant to which we granted to Pierre Fabre an exclusive, field-limited license to commercialize and distribute Ebvallo in Europe and select emerging markets in the Middle East, Africa, Eastern Europe and Central Asia (the Initial Territory) following regulatory approval. As contemplated by the Pierre Fabre Commercialization Agreement, we entered into (i) a Manufacturing and Supply Agreement (ii) a Pharmacovigilance Agreement (iii) and a Quality Agreement, in each case, with Pierre Fabre to further advance our partnership with Pierre Fabre. In September 2022, we amended the Pierre Fabre Commercialization Agreement and received an additional $30 million milestone payment from Pierre Fabre following EC approval of Ebvallo for EBV+ PTLD and subsequent filing of the MAA transfer to Pierre Fabre, in exchange for, among other things, a reduction in: (i) royalties we are eligible to receive as a percentage of net sales of Ebvallo in the Initial Territory, and (ii) the supply price mark up on Ebvallo purchased by Pierre Fabre. Additionally, we agreed to extend the time period for provision of certain services to Pierre Fabre under the Pierre Fabre Commercialization Agreement. In December 2022, we entered into a Purchase and Sale Agreement (HCRx Agreement) with HCR Molag Fund L.P. (HCRx,) a Delaware limited partnership. Pursuant to the terms of the HCRx Agreement, we received a total investment amount of $31.0 million in exchange for granting HCRx the right to receive a portion of the tiered, sales-based royalties for Ebvallo, in amounts ranging from the mid-single digits to significant double digits, and certain milestone payments, both related to the Initial Territory and otherwise payable to us by Pierre Fabre. The total royalties and milestones payable to HCRx related to the Initial Territory under the HCRx Agreement are capped between 185% and 250% of the total investment amount by HCRx, dependent upon the timing of such royalty and milestone payments to HCRx.

On October 31, 2023, we entered into an amended and restated Pierre Fabre Commercialization Agreement (A&R Commercialization Agreement), pursuant to which we expanded Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute tab-cel (Ebvallo) to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of $20.0 million for the expanded exclusive license grant, for which such cash was received in January 2024. We will also be entitled to receive an aggregate of up to $620.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory including up to $100.0 million in potential regulatory milestones through approval by the United States Food and Drug Administration (FDA) of a biologics license application (BLA) for tab-cel. Of the $100.0 million in potential regulatory milestones, we expect to receive $20.0 million in April 2024 based on the positive pre-BLA meeting, an additional $20.0 million in connection with BLA acceptance, and up to $60.0 million in potential regulatory milestones in connection with BLA approval. We are eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel in each such country. Royalty payments may be reduced in certain specified customary circumstances. Royalties and milestones from the commercialization of Ebvallo in the Initial Territory remain subject to the HCRx Agreement.

During the applicable period specified in the A&R Commercialization Agreement, we will be responsible, at Pierre Fabre's cost, to continue conducting the ongoing Phase 3 ALLELE clinical study and the Phase 2 multi-cohort clinical study. We will also be responsible, at Pierre Fabre's cost, for certain other activities directed to obtaining regulatory approval in the United States for tab-cel for EBV-associated post-transplant lymphoproliferative disease pursuant to the terms of the A&R Commercialization Agreement. Pierre Fabre will be responsible, at its cost, for obtaining and maintaining all other required regulatory approvals and for commercialization and distribution of tab-cel in the Territory, including conducting any other clinical study required.

Prior to the transfer of manufacturing responsibility to Pierre Fabre, we will be responsible for manufacturing and supplying tab-cel to Pierre Fabre for commercialization in the Territory at cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab-cel in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of i) the date on which all activities relating to the transfer of tab-cel manufacturing, pursuant to the A&R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, throughout the remainder of the term of the A&R Commercialization Agreement. Pierre and we are to use commercially reasonable efforts to achieve such transition prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the first BLA.

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

Our research facilities in Thousand Oaks, California (ARC) and Aurora, Colorado contain our translational and preclinical sciences, analytical development and process science functions. These facilities support our product pipeline, process development and leverage our allogeneic cell therapy platform to drive innovation.

In January 2022, we entered into an asset purchase agreement with FUJIFILM Diosynth Biotechnologies California, Inc. (FDB) and, for certain limited purposes, FUJIFILM Holdings America Corporation, to sell all of the Company's right, title and interest in and to certain assets related to the Atara T-Cell Operations and Manufacturing facility (ATOM Facility) located in Thousand Oaks, California for $100 million in cash, subject to potential post-closing adjustments pursuant to the asset purchase agreement (the Fujifilm Transaction). The closing of the Fujifilm Transaction occurred on April 4, 2022. We also entered into a Master Services and Supply Agreement with FDB (Fujifilm MSA) that became effective upon the closing and could extend for up to ten years. Pursuant to the Fujifilm MSA, FDB will supply us with specified quantities of our cell therapy products (if approved) and product candidates, manufactured in accordance with cGMP standards. The Fujifilm MSA does not obligate us to purchase products and product candidates exclusively from FDB.

We also work with Charles River Laboratories (CRL) pursuant to a Commercial Manufacturing Services Agreement (CRL MSA) that we entered into in December 2019. Pursuant to the CRL MSA, CRL provides manufacturing services for our product and certain intermediates. We further amended the CRL MSA to extend the term until the earlier of March 31, 2024 or upon receipt of certain batches of our product and product candidates. We are currently in negotiations with CRL for a new commercial drug product supply agreement to be effective upon the expiration of the CRL MSA. However, there can be no assurance that we will be able to enter into a new commercial drug product supply agreement with CRL on terms favorable or acceptable to us, or at all. If we are

unable to enter into a new commercial drug product supply agreement or extend the CRL MSA, we may need to identify alternative sources of drug product supply.

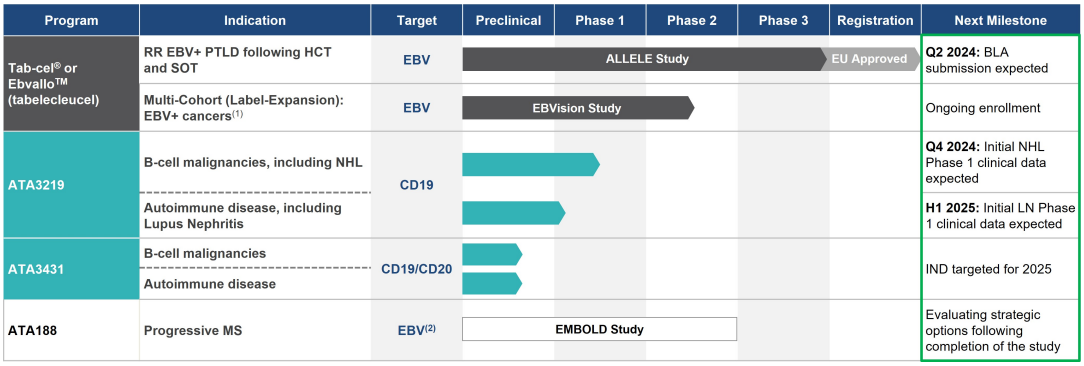
We have non-cancellable minimum commitments for products and services, subject to agreements with a term of greater than one year, with clinical research organizations and CMOs.

In November 2023, we announced a reduction in force of approximately 30% of our workforce at that time. This workforce reduction resulted in total restructuring charges of $6.7 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California Worker Adjustment and Retraining Notification (WARN) Act. In most cases, the severance payments were paid as a lump sum in January 2024. All of the severance costs represent cash expenditures.

In January 2024, we announced another reduction in force of approximately 25% of total workforce. We expect to recognize approximately $4.5 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2024. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from February 2024 through January 2025. The majority of the associated costs represent cash expenditures.

Pipeline

Our pipeline is summarized below:



Excluding Ebvallo™ in EU, these investigational agents are not approved by any regulatory agencies and efficacy and safety have not been established

EBV+ PTLD: EBV-Associated Post-Transplant Lymphoproliferative Disease; RR: rituximab relapsed/refractory; HCT: allogeneic hematopoietic cell transplant; SOT: solid organ transplant; NHL: non-Hodgkin's lymphoma

Atara has entered into an agreement with Pierre Fabre to commercialize tab-cel® for EBV+ cancers worldwide

Other programs: EBV vaccine and other hematological malignancies and solid tumor AlloCAR T programs

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

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

Ebvallo™ (Tab-cel®)

EBV+ PTLD

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

Historical studies suggest a high unmet medical need for improved therapies in patients with EBV+ 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 approximately 1.7 months, and for patients with EBV+ PTLD following SOT who have failed rituximab-based first line therapy, the median overall survival is approximately 3.3 months. The use of chemotherapy in patients with EBV+ PTLD who have failed rituximab is frequently associated with significant rates of treatment-related mortality due to the frailty of the patients and severe toxicities associated with chemotherapy. Based on our market research, we estimate there were several hundred EBV+ PTLD patients who failed rituximab or rituximab plus chemotherapy in the U.S. in 2019.

Tab-cel® (Ebvallo™) for EBV+ PTLD

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

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

Tab-cel has received Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration (FDA) for the treatment of patients with EBV+ PTLD after HCT who have failed rituximab and orphan designation in the U.S. and European Union (EU) for the treatment of patients with EBV+ PTLD following HCT or SOT.

In clinical studies conducted at MSK that have enrolled patients 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 two-year overall survival of approximately 83% in two separate clinical studies. In the setting of EBV+ PTLD after SOT in patients who have failed rituximab, similar results were observed, with two-year overall survival of approximately 86% in tab-cel-treated patients. A response rate of greater than or equal to 50% was observed in HCT and SOT patients in these studies.

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

In the third quarter of 2020, we completed an interim analysis for the ALLELE study. Data from the interim analysis showed a 50 percent objective response rate (ORR) to tab-cel with independent oncologic and radiographic assessment (IORA) in patients with relapsed-refractory EBV+ PTLD following HCT or SOT, that had reached at least six months follow-up after the ORR assessment. This ORR is consistent with previously published investigator assessed data. The tab-cel safety profile is also consistent with previously published data, with no new safety signals. In December 2022, we presented updated interim analysis and safety results from the ALLELE study and updated efficacy and safety data from two single-center, open-label studies, and multicenter expanded access program in patients with EBV+ Leiomysosarcomas at the 2022 American Society of Hematology Annual Meeting. In December 2023, we presented new data for patients with relapsed or refractory (r/r) or treatment-naïve EBV+ PTLD involving the central nervous system following SOT or HCT. An ORR of 77.8% was observed in 18 central nervous system (CNS) EBV+ PTLD patients including first line PTLD, and the estimated one-year overall survival rate (OS) was 70.6%. The one-year OS for responders was 85.7% versus 0% for non-responders. In January 2024, data from the ALLELE study that was published in *The Lancet Oncology* showed a 51.2% objective response rate and 23-month median duration of response in r/r EBV+ PTLD patients and that tab-cel was well tolerated with no events of graft-versus-host disease as related to tab-cel.

In October 2021, we entered into the Pierre Fabre Commercialization Agreement, pursuant to which we granted to Pierre Fabre an exclusive, field-limited license to commercialize and distribute Ebvallo in the Initial Territory. In September 2022, we amended the Pierre Fabre Commercialization Agreement to receive an additional $30 million milestone payment from Pierre Fabre in exchange for a reduction in royalties and the supply price mark up on Ebvallo purchased by Pierre Fabre. See section 'Terms of Certain License and Collaboration Agreements' below for additional details. In December 2022, we sold a portion of our right to receive royalties and certain milestones in Ebvallo under the Pierre Fabre Commercialization Agreement to HCRx for a total investment amount of $31.0 million, subject to a repayment cap between 185% and 250% of the total investment amount by HCRx.

On October 31, 2023, we entered into the A&R Commercialization Agreement, which became effective in December 2023. Pursuant to the A&R Commercialization Agreement, Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute tab-cel (Ebvallo) will be expanded to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of $20.0 million for the expanded exclusive license grant, for which such cash was received in January 2024. We will also be entitled to receive an aggregate of up to $620.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory, including up to $100.0 million in potential regulatory milestones through BLA approval. Of the $100.0 million in potential regulatory milestones, we expect to receive $20.0 million in April 2024 based on the positive pre-BLA meeting, an additional $20.0 million in connection with BLA acceptance, and up to $60.0 million in potential regulatory milestones in connection with BLA approval.

We are eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel in each such country. Royalty payments may be reduced in certain specified customary circumstances. Royalties and milestones from the commercialization of Ebvallo in the Initial Territory remain subject to the HCRx Agreement.

In November 2021, we submitted an EU marketing authorization application (MAA) for tab-cel in patients with EBV+ PTLD. In December 2022, the EC granted marketing authorization for Ebvallo under the "exceptional circumstances" regulatory pathway as a monotherapy for the treatment of adult and pediatric patients two years of age and older with r/r EBV+ PTLD who have received at least one prior therapy. For SOT patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate. Our request to transfer the marketing authorization for Ebvallo to Pierre Fabre was adopted by the EC in February 2023. Pierre Fabre commenced Ebvallo launch activities in the first European countries in the first quarter of 2023 and is progressively launching Ebvallo on a country-by-country basis. Under the "exceptional circumstances" marketing authorization, Pierre Fabre is subject to annual reassessments of certain ongoing post-marketing obligations to continue confirmation of the benefits of Ebvallo. The annual reassessments will determine whether the Ebvallo marketing authorization should be maintained, changed, or suspended, based on Pierre Fabre's fulfillment of post-marketing obligations and the risk/benefit profile of Ebvallo.

In October 2022, we filed the MAA for Ebvallo with the Medicines and Healthcare Products Regulatory Authority (MHRA) in the United Kingdom (UK). In May 2023, the MHRA granted Ebvallo marketing authorization in the UK for the treatment of patients with EBV+ PTLD and the marketing authorization was subsequently transferred to Pierre Fabre.

We have performed extensive studies demonstrating analytical comparability between the tab-cel manufacturing process versions used for the pivotal ALLELE study and that intended for commercialization. Comprehensive comparability analyses covered 21 key attributes for potency, purity and alloreactivity. We believe analytic comparability between tab-cel process versions has been demonstrated based on well-established statistical methodology and application of International Council for Harmonization (ICH) guidelines and is further supported by significant and consistent clinical experience. These comparability data analyses were submitted to the EMA through our MAA filing. EMA stated in its assessment report issued following approval of the MAA for tab-cel by the EC that it considered comparability of the intended commercial product with the clinically used product to be shown.

We have been engaged in discussions with the FDA regarding a potential biologics license application (BLA) submission for tab-cel in the United States, including on (i) the content of chemistry, manufacturing and controls (CMC) module 3 and the assessment of comparability between the product used in the pivotal ALLELE study and that intended for commercialization and (ii) the clinical data package requirements.

In February 2022, we held a Type B CMC meeting with the FDA to discuss comparability between the intended commercial and pivotal clinical trial process versions. This meeting did not result in alignment on comparability and the FDA initially recommended we conduct a clinical study with commercial product as the FDA did not agree that comparability has been demonstrated between product used in the pivotal ALLELE study and the intended commercial product. Following further discussions, the FDA recommended a potential path to a BLA submission without the need for a new clinical study.

We subsequently held another meeting with the FDA to discuss topics relating to CMC, which culminated in clear guidance and agreement on specific CMC module 3 requirements for a potential BLA submission. Following this meeting, we filed an amendment to the Investigational New Drug (IND) application for tab-cel to provide additional CMC information requested by the FDA.

In 2023, we held a number of meetings with the FDA on clinical aspects and CMC for a potential BLA submission for tab-cel. Following such discussions, we aligned with the FDA on analytical comparability between manufacturing process versions of tab-cel. This alignment supports our ability to pool the pivotal clinical trial data from different process versions in a tab-cel BLA submission.

We recently held a pre-BLA meeting with the FDA to discuss various aspects of our proposed BLA submission, which supports our plan to submit the tab-cel BLA in the second quarter of 2024. Of the $100.0 million in potential regulatory milestones that we may be entitled to receive through approval from Pierre Fabre pursuant to the terms of the A&R Commercialization Agreement, we expect to receive $20.0 million in April 2024 based on the positive pre-BLA meeting, an additional $20.0 million in connection with BLA acceptance, and up to $60.0 million in potential regulatory milestones in connection with BLA approval.

Tab-cel Multi-Cohort Study

We continue to pursue development of tab-cel in additional patient populations, with a primary focus on immunodeficiency-associated lymphoproliferative diseases (IA-LPDs), given the commonality of their EBV-driven mechanism of disease in immunocompromised patients, high unmet medical needs and positive clinical data to date with tab-cel. In patients where previous treatments have failed, the objective response rates, including complete response, were 33.3% (three out of nine patients) in AID-LPD and 37.5% (three out of eight patients) in PID-LPD groups. Tab-cel was generally well-tolerated with a favorable safety profile consistent with previously published clinical studies. These clinical data demonstrated that tab-cel was well-tolerated and showed encouraging clinical activity in this patient population, with objective response rates ranging from 50% (two out of four patients) to 80% (four out of five patients). The overall survival (OS) rate at one year in patients with EBV viremia treated in the EAP-201 study was 100 percent for a median follow-up of 14.6 months (min 12.2, max 17.8).

In the third quarter of 2020, we initiated a Phase 2 multi-cohort study which comprises a total of five patient populations, including IA-LPDs and other EBV-driven diseases, in both the U.S. and EU. We continue to enroll patients in this study. We are investigating additional label expansion opportunities with our Phase 2 multi-cohort study. In December 2023, we presented combined analysis that included the first reported data from our Phase 2 multi-cohort study at the European Society for Medical Oncology Immuno-Oncology annual congress that demonstrated a 77.8% ORR in 18 CNS EBV+ PTLD patients including first line PTLD.

ATA3219

We are developing ATA3219, an allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies and autoimmune diseases, leveraging our next-generation 1XX CAR co-stimulatory domain and EBV T-cell platform and does not require TCR or HLA gene editing. ATA3219 combines the natural biology of unedited T cells with the benefits of an allogeneic therapy. It consists of allogeneic EBV-sensitized T cells that express a CD19 CAR construct for the treatment of CD19+ r/rB-cell malignancies, including B-cell non-Hodgkin's lymphoma (NHL) and B-cell mediated autoimmune diseases including systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis (LN)). ATA3219 has been optimized to offer a potential best-in-class profile, featuring off-the-shelf availability. It incorporates multiple clinically validated technologies including a modified CD3ζ signaling domain (1XX) that optimizes expansion and mitigates exhaustion, provides enrichment during manufacturing for a less differentiated phenotype for robust expansion and persistence and retains the endogenous T-cell receptor without gene editing as a key survival signal for T cells which contribute to persistence.

Data from preclinical studies for ATA3219 suggest enhanced functional persistence, polyfunctional phenotype and efficient targeting of CD19-expressing tumor cells both in vitro and in vivo with a manufacturing process that focuses on T-cell stemness. Additional in vitro data demonstrate the CD19 antigen-specific functional activity of ATA3219 and CAR-mediated activity against B cells from SLE patients, leading to robust CD19-specific B-cell depletion compared to controls. This preclinical data was submitted as part of a late-breaking abstract which was accepted for poster presentation at the upcoming International Society for Cell & Gene Therapy meeting to be held May 29-June 1, 2024.

Based on academic data from a clinical study, an EBV T-cell platform has the potential to generate off-the-shelf, allogeneic CAR T immunotherapies with high response rates, durable responses and low risk of toxicity that can be rapidly delivered to patients.

Our EBV CD19 CAR T program incorporates multiple clinically validated technologies designed for a memory phenotype, robust expansion, and retains the endogenous T-cell receptor without gene editing as a key survival signal for T cells contributing to functional persistence. We continue to make progress on the ATA3219 manufacturing process for scale-up.

Data from an academic study (Curran et al ASH 2023) that used allogeneic EBV CAR T cells (CD28/CD3ζ co-stimulatory domain), demonstrated proof of principle for Atara's allogeneic CAR T approach with overall survival up to 3 years in post-transplant B-cell malignancy patients. Atara's ATA3219 builds upon this study with an improved process and construct that leverages multiple clinically validated technologies featuring a less differentiated phenotype and a novel 1XX costimulatory domain. We continue to make progress on the ATA3219 manufacturing process for scale-up.

In July 2023, we received a Safe to Proceed letter from the FDA in response to our IND submission for ATA3219 in r/r B-cell NHL. We initiated enrollment of a multi-center, Phase 1 open-label, dose escalation clinical trial for ATA3219 in NHL, including large B-cell lymphomas, follicular lymphoma, or mantle cell lymphoma, with initial clinical data anticipated in the fourth quarter of 2024.

In February 2024, we received a Safe to Proceed letter from the FDA in response to our IND submission for use of ATA3219 as a monotherapy for the treatment of SLE with LN and expect to initiate a Phase 1 study to evaluate the safety and preliminary efficacy of ATA3219 in the second half of 2024. Initial data is anticipated in the first half of 2025.

Additional Programs and Platform Expansion Activities

In addition to the prioritized programs described above, we have a number of preclinical programs.

Our CAR T immunotherapy pipeline includes ATA3431, an allogeneic, bispecific CAR directed against CD19 and CD20 for B-cell malignancies and autoimmune disease, leveraging our 1XX CAR co-stimulatory domain and EBV T-cell platform and does not require gene TCR or HLA gene editing. ATA3431 is enriched for central memory CAR T cells and in December 2023, we presented preclinical data that demonstrated early evidence of antitumor activity, long-term persistence, and superior tumor growth inhibition compared to an autologous CD19/CD20 CAR T benchmark at the 65th American Society of Hematology Annual Meeting and Exposition 2023. We are progressing toward an IND submission and expect to file an IND submission for ATA3431 in 2025.

We are also collaborating with QIMR Berghofer to develop a potential next generation EBV vaccine which is differentiated from earlier EBV vaccine efforts that solely focused on B cell responses to EBV. We also retain the rights to ATA188, an allogeneic T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). We have paused development on ATA188 while we explore strategic options for this asset. We have also discontinued some programs and will return the programs to our collaborators. For example, in February 2024, we notified MSK that we will return the ATA2271 and ATA3271 programs targeting mesothelin to MSK.

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 also continue to evaluate opportunities to license or acquire additional product candidates or technologies to enhance our existing platform.

Competition

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

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

EBV+ PTLD

There are currently no FDA-approved products for the treatment of EBV+ PTLD, and there are no EC-approved products for this indication except for Ebvallo. However, we are aware that some marketed products and therapies are used off-label by some healthcare professionals and institutions in the treatment of EBV+ PTLD, such as rituximab and combination chemotherapy regimens.

In addition, a number of companies and academic institutions are developing product candidates for EBV+ PTLD and other EBV-driven diseases including: Viracta Therapeutics, Inc., which is conducting a pivotal, Phase 2 clinical study for nanatinostat (formerly named tractinostat, or VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas; AlloVir (formerly known as ViraCyte), which has completed a Phase 2 clinical study for posoleucel (ALVR105), an allogeneic, multi-virus T-cell product that targets six viruses in allogeneic HSCT recipients with ≥1 treatment-refractory infection, including EBV, and is conducting two Phase 3 clinical trials for Virus-Associated Hemorrhagic-Cystitis, as well as a Phase 3 trial for the prevention of BKV, CMV, AdV, EBV, HHV06 and JCV in post-allogeneic HSCT patients.

CAR T Program

There are currently six autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel), Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus™ (brexucabtagene autoleucel) and Bristol-Myers Squibb's Breyanzi® (lisocabtagene maraleucel) and Abecma (idecabtagene vicleucel) with 2seventy bio and Johnson & Johnson and Legend Biotech's Carykti™ (ciltacabtagene autoleucel). There are many CAR-mediated cell therapies in development, and, although the majority are autologous, they also include allogeneic and off-the-shelf cell therapies. There are multiple allogeneic CAR platforms being developed with differences in approaches to minimize instances of donor cells recognizing the patient's body as foreign or rejection of the donor cells by the patient's body. These approaches include the use of gene-editing to remove or inhibit the TCR and the use of cell types without a TCR. The majority of clinical stage allogeneic CAR programs utilize alpha beta T cells as the cell type and gene editing of the T-cell receptor and HLA as the preferred technology approach, however, other strategies are also in development. It is possible that some of these other approaches will have more favorable characteristics than the approach we utilize, which would result in them being favored by potential partners or customers over our products. Depending on the diseases (such as autoimmune diseases) that we target in the future, we may face competition from both autologous and allogeneic CAR therapies and other modalities (e.g., small molecules, antibodies, bispecifics) in the indication of interest.

Terms of Certain License and Collaboration Agreements

Out-licensing

Pierre Fabre Commercialization Agreement

In October 2021, we entered into the Pierre Fabre Commercialization Agreement, pursuant to which we granted to Pierre Fabre an exclusive, field-limited license to commercialize and distribute Ebvallo in Europe and select emerging markets in the Initial Territory following regulatory approval. In September 2022, we amended the Pierre Fabre Commercialization Agreement and received an additional $30 million milestone payment from Pierre Fabre following EC approval of Ebvallo for EBV+ PTLD and subsequent filing of the MAA transfer to Pierre Fabre, in exchange for, among other things, a reduction in: (i) royalties we are eligible to receive as a percentage of net sales of Ebvallo in the Initial Territory, and (ii) the supply price mark up on Ebvallo purchased by Pierre Fabre. Additionally, we agreed to extend the time period for provision of certain services to Pierre Fabre under the Pierre Fabre Commercialization Agreement. In December 2022, we sold a portion of our right to receive royalties and certain milestones in Ebvallo under the Pierre Fabre Commercialization Agreement to HCRx for a total investment amount of $31.0 million, subject to a repayment cap between 185% and 250% of the total investment amount by HCRx. See Note 6 – "Liability Related to the Sale of Future Revenues" in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statement and Supplementary Data of this report for further information related to the agreement with HCRx.

In October 2023, we entered into an A&R Commercialization Agreement, pursuant to which we expanded Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute Ebvallo to include the Additional Territory in addition to the Initial Territory, subject to our performance of certain obligations as described below.

During the applicable period specified in the A&R Commercialization Agreement, we will be responsible, at Pierre Fabre's cost, to continue conducting the ongoing Phase 3 ALLELE clinical study and the Phase 2 multi-cohort clinical study. We will also be responsible, at Pierre Fabre's cost, for certain other activities directed to obtaining regulatory approval in the United States for tab-cel for EBV-associated post-transplant lymphoproliferative disease pursuant to the terms of the A&R Commercialization Agreement. Pierre Fabre will be responsible, at its cost, for obtaining and maintaining all other required regulatory approvals and for commercialization and distribution of tab-cel in the Additional Territory, including conducting any other clinical study required. We will own any intellectual property rights developed solely by us under the Agreement.

As part of the Pierre Fabre Commercialization Agreement, we formed a joint steering committee (JSC) with Pierre Fabre that provides oversight, decision making and implementation guidance regarding the commercialization activities, the responsibilities of which has been expanded to cover the incremental scope of the A&R Commercialization Agreement.

Pierre Fabre paid us an upfront cash payment of $45.0 million for the exclusive license grant for the Initial Territory in the fourth quarter of 2021. In December 2022, we met the contractual right to receive $40.0 million in milestone payments upon certain regulatory milestones, for which the cash was received in January 2023. Subject to the terms of the royalty purchase agreement with HCRx, as described in Note 6 – "Liability Related to the Sale of Future Revenues" in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report, we are entitled to receive an aggregate of up to $308.0 million in remaining milestone payments upon achieving certain regulatory and commercial milestones in addition to double-digit tiered royalties as a percentage of net sales of Ebvallo in the Initial Territory, until the later of 12 years after the first commercial sale in such country, the expiration of specified patent rights, or the expiration of all regulatory exclusivity for such product on a country-by-country basis. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of $20.0 million for the expanded exclusive license grant, for which the cash was received in January 2024. We will also be entitled to receive an aggregate of up to $620.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory, including up to $100.0 million in potential regulatory milestones through BLA approval. Of the $100.0 million in potential regulatory milestones, we expect to receive $20.0 million in April 2024 based on the positive pre-BLA meeting, an additional $20.0 million in connection with BLA acceptance, and up to $60.0 million in potential regulatory milestones in connection with BLA approval. In addition, we will be eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Additional Territory until the later of 12 years after the first commercial sale in such country, the expiration of specified patent rights in such country, or the expiration of all regulatory exclusivity for such Product in such country.

We have entered into a separate manufacturing and supply agreement with Pierre Fabre for us to manufacture Ebvallo for Pierre Fabre to use in the Initial Territory based on a fixed price through December 31, 2023 and at a price equal to cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Prior to the transfer of manufacturing responsibility to Pierre Fabre, we will be responsible for manufacturing and supplying tab-cel to Pierre Fabre for commercialization in the Territory. Upon the Manufacturing Transition Date and through the remainder of the term of the A&R Commercialization Agreement, Pierre Fabre will be responsible, at its cost, for the manufacture and supply of tab-cel in the Territory. Without transfer of the manufacturing technology, no other party can manufacture tab-cel.

We are also responsible for cell selection services in the Initial Territory at our cost for a certain period of time, unless the parties agree to transfer the related cell selection technology to Pierre Fabre prior to this date, and we are responsible for cell selection services at the sole expense of Pierre Fabre for a certain period of time in the Additional Territory. After this period of time, if we agree to continue to provide cell selection services in the Territory, it shall be at the sole expense of Pierre Fabre. Cell selection is the process of identifying the appropriate cell line from available inventory to be used for a patient. Without transfer of the cell selection technology, no other party can provide such services.

In-licensing

MSK Agreements

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

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

In March 2021, we amended and restated our license agreement with MSK to terminate our license to certain rights and license additional know-how rights not otherwise covered by our existing agreements.

In February 2024, we notified MSK that we intend to terminate our licenses to the ATA2271 and ATA3271 programs targeting mesothelin.

QIMR Berghofer Agreements

In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer. Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive and worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology in June 2018. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019 to terminate our license to certain rights related to cytomegalovirus (CMV). In addition, we further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2020 to terminate our license to certain rights related to BK polyomavirus and JC polyomavirus. In December 2021, we further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer to terminate our license to certain rights related to HPV associated cancers. We refer to our December 2021 fourth amended and restated license agreement with QIMR Berghofer as the QIMR License Agreement and our December 2021 fourth amended and restated research and development collaboration agreement with QIMR Berghofer as our QIMR Collaboration Agreement.

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

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 and other regulatory filings related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Some of patents, trademarks, trade secrets, know-how and other intellectual property rights we rely on are owned by us and others are in-licensed from our partners. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license. Additionally, we expect to benefit from a variety of statutory frameworks in the U.S., Europe and other countries that relate to the regulation of biosimilar molecules and orphan drug status. These statutory frameworks provide certain periods of regulatory exclusivity for qualifying molecules. See "Government Regulation."

Patents

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

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

availability of extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

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

Our global patent estate consists of both solely-owned and in-licensed patents and patent applications, is directed to compositions of matter and/or associated methods, including methods of treatment, and consists of 19 patent families having a total of more than 230 issued patents or patent applications. Our patents and patent applications (if issued) are expected to expire between 2024 and 2044, not inclusive of any patent term extension that may be available in any associated jurisdiction.

Trade Secrets

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

Trademarks

We also rely upon trademarks to develop and maintain our competitive position, and we continue to pursue and obtain trademark rights relating to our business. We have a vigorous global program of trademark registration and enforcement to maintain and strengthen the value of our trademarks and prevent the unauthorized use of those trademarks. Our global trademark portfolio consists of six different trademark families comprised of more than 70 registrations and pending applications.

Government Regulation and Product Approval

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

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, tracking and tracing, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the U.S. and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that

imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

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

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

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

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

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

•*Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients rather than healthy human volunteers.

•*Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

•*Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for marketing approval and product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted, and in some cases are required by the FDA, after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and to investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk in humans exposed to the drug, laboratory animal testing or in vitro testing that suggest a significant risk to human patients, or any clinically important increase in the rate of a serious expected adverse reaction over the rate listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the product candidate to which the research patients are being exposed poses an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

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

U.S. BLA Review and Approval Processes

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

Under the Prescription Drug User Fee Act, as amended (PDUFA), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees for licensed innovator biological products on an annual basis. PDUFA also imposes an annual program fee for innovator biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for innovator biological products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also determines whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit and obtain approval for a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

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

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

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

In addition, the Pediatric Research Equity Act (PREA) requires applicants to study certain drugs and biological products in relevant pediatric subpopulations, with the potential of obtaining pediatric labeling for the product, if the drug is found to be safe and effective for use in children. With enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, sponsors must submit an initial pediatric study plan in the BLA. Pediatric study plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation and must be agreed upon by the FDA. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may grant deferrals for submission of data or full or partial waivers for pediatric studies, including the study of all pediatric patients or subpopulations based on age on its own initiative or at the request of the applicant. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation. For example, Section 505B of the U.S. Food, Drug and Cosmetic Act, as amended by the FDA Reauthorization Act in 2020, requires that any original NDA or BLA submitted on or after August 18, 2020 for a new active ingredient contain reports on molecularly targeted pediatric cancer investigations unless the requirement is waived or deferred, if the drug that is the subject of the application is: (1) intended for the treatment of an adult cancer, and (2) directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. This requirement applies even if the adult cancer indication does not occur in the pediatric population and even if the drug is for an adult indication for which orphan designation has been granted. Therefore, the BLA of any product we develop that is determined to be substantially relevant to the growth or progression of a pediatric cancer, even if the drug has been designated as an orphan drug for an adult indication, must contain reports on molecularly targeted pediatric cancer investigations unless such investigations are waived or deferred.

Orphan Drug Designation in the U.S.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

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

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

Expedited Development and Review Programs in the U.S.

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address an unmet medical need for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. For a product that

has received fast track designation, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted. A sponsor seeking a rolling submission must provide a schedule for the submission of each section of the BLA, and the FDA must agree to the rolling submission and that the schedule is acceptable. In addition, the sponsor must pay any required user fees upon submission of the first section of the BLA. Submission of sections of a BLA on a rolling basis does not guarantee that the FDA will begin their review of these sections upon receipt or even before the BLA submission is deemed to be complete. Therefore, a rolling BLA submission may not result in a faster timeline to marketing approval. Additionally, a rolling BLA submission has no bearing on whether or not a product candidate is ultimately approved.

Any product, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it is intended for treatment of a serious condition and has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. The FDA intends to take action on applications under priority review within 6 months of the application filing date compared with 10 months from the filing date for standard review.

Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies to demonstrate clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

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

Fast Track designation, priority review, RMAT and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. The FDA may revoke any of these designations if the product no longer meets applicable criteria.

Post-Approval Requirements in the U.S.

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

In addition, the distribution of prescription drug products, including most biological products that require a prescription, are subject to the Prescription Drug Marketing Act, or the PDMA, which regulates the distribution of drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription drug product samples and impose requirements to ensure accountability in distribution.

Furthermore, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

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

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act (BPCIA) amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish that its molecule is highly similar to an approved innovator biologic, notwithstanding minor differences in clinically inactive components, and shows no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, which can generally be shown through analytical studies, animal studies, and a clinical study or studies. Separately, a product that is biosimilar to the reference product is considered interchangeable if the product demonstrates that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the interchangeable biosimilar and the reference biological product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. If a product is shown to be biosimilar or interchangeable with an FDA-approved reference biologic, this can potentially reduce the cost and time required to obtain approval to market the biosimilar or interchangeable product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles and have slowed implementation of the BPCIA by the FDA.

The BPCIA, however, bars the submission of BLAs for biosimilars to an approved application until four years after the licensure date for the reference biologic. In addition, the FDA may not approve biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. During this 12-year period of reference product exclusivity, another company may obtain FDA licensure and market a competing version of the reference product if the FDA approves a full BLA for the competing

product containing that applicant's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests, and the innovator company completes pediatric clinical investigations of the product.

The development and, if approved, marketing of biosimilars is subject to user fees under the Biosimilar User Fee Amendments of 2022 (BsUFA), which currently apply through September 2027 and may be renewed or amended thereafter. Sponsors must submit an initial biosimilar biological product development (BPD) fee on the earlier of the submission of an IND or within 7 calendar days of FDA granting a first BPD meeting, and annually thereafter until the sponsor submits a BLA that is accepted for filing, or the sponsor discontinues participation in the BPD program. FDA may also remove a sponsor from the BPD program if the sponsor has failed to pay annual BPD fees for a period of 2 consecutive fiscal years. Sponsors who discontinue participation in the BPD program but want to reengage FDA on product development must also pay all prior assessed BPD fees still owed and a reactivation fee and will be subject to annual BPD fees. Once a sponsor submits a BLA for a biosimilar, they are subject to application fees. And, once a biosimilar BLA is approved, the sponsor is subject to annual program fees. The FDA amends the specific fee amounts under BsUFA on an annual basis.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, there has been discussion of whether Congress should reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation of the BPCIA is subject to significant uncertainty.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Reimbursement of Approved Products in the U.S.

In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which the costs of such products will be covered by third party payors, such as government health programs, commercial insurance and managed healthcare organizations. Third party payors determine which medications they will cover and establish reimbursement amounts. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Interim reimbursement amounts for new drugs, if applicable, may also be insufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third party payors in the U.S. Third party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third party payors will decide with respect to coverage and reimbursement for our drug products.

These third party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs,

including price controls, restrictions on reimbursement and requirements for substitution of generic products. In the U.S. there have been several 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. For example, included in the Consolidated Appropriations Act of 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the Departments of Health and Human Services, Labor and the Treasury. Additionally, on July 9, 2021, President Biden issued an Executive Order to promote competition in the U.S. economy that included several initiatives addressing prescription drugs. Among other provisions, the Executive Order stated that the Biden administration will "support aggressive legislative reforms that would lower prescription drugs, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms." In response to the Executive Order, on September 9, 2021, the Department of Health and Human Services issued a Comprehensive Plan for Addressing High Drug Prices that identified potential legislative policies and administrative tools that Congress and the agency can pursue in order to make drug prices more affordable and equitable, improve and promote competition throughout the prescription drug industry, and foster scientific innovation. Most recently, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022 (IRA), which implements substantial changes to the Medicare program, including drug pricing reforms and changes to the Medicare Part D benefit design. Among other reforms, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap benefit annual out-of-pocket spending at $2,000 while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services. 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 (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 a covered outpatient drug 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, outpatient drugs (i.e., drugs typically dispensed by a pharmacy and 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, subject to CMS rules and requirements, 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 in accordance with CMS rules and requirements. Subject to certain payment adjustments and limits, Medicare generally pays for Part B covered drugs based on a percentage of manufacturer-reported average sales price.

Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule (FSS). FSS participation is required for a drug product to be covered and paid for by certain federal agencies and for coverage under Medicaid, Medicare Part B and the PHS pharmaceutical pricing program, commonly referred to as the 340B Drug Pricing Program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended to not exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than inflation.

To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a

disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Affordable Care Act), which included changes to the coverage and payment for drug products under government health care programs. Since its enactment, there have been judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, 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 coverage gap discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In June 2021, the U.S. Supreme Court dismissed a lawsuit challenging the constitutionality of certain aspects of the ACA, without ruling on the merits of the constitutionality arguments. Additionally, the American Rescue Plan of 2021, Pub. L. No. 117-2, enacted on March 11, 2021, temporarily increased premium tax credit assistance for those eligible for subsidies for 2021 and 2022 and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. Most recently, the IRA extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025.It is unclear how the healthcare reform measures of the Biden administration and any future litigation will impact the Affordable Care Act and our business.

U.S. Health Care Laws

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

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

- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws that impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; the FDCA and PHSA, which prohibit the misbranding and adulteration of biological products that are regulated as drugs, and which regulate the marketing of biological products;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information as well as their covered subcontractors;

- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, certified nurse midwives and U.S. teaching hospitals, as well as

ownership and investment interests held by physicians 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, including but not limited to the UK Bribery Act 2010, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers;

•state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; including those that 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 as well as those that require the registration of pharmaceutical sales representatives. Some state laws require the protection of the privacy and security of health information in a manner that may differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, California enacted the California Consumer Privacy Act (CCPA), effective January 1, 2020, which was recently amended by the California Privacy Rights Act of 2020 (CPRA); and

•similar healthcare and privacy laws and regulations in the European Economic Area (EEA), the UK and other jurisdictions, such as, the General Data Protection Regulation (EU) 2016/679, which impose obligations and restrictions on the collection and use of personal information relating to individuals located in the EEA and the UK (including health information).

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

Foreign Regulation

In addition to regulations in the U.S., we are subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of our product candidates and interactions with healthcare professionals. 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 trial application (CTA), which is similar to an IND in the U.S., prior to the commencement of human clinical studies. In the EU, for example, in accordance with the requirements of the EU Clinical Trials Regulation 536/2014 (CTR), a CTA must be submitted to the centralized EU Portal, Clinical Trials Information System (CTIS) for review by each country in which the sponsor intends to conduct the clinical study. As part of the application process under the CTR, the sponsor proposes a reporting Member State, which coordinates the validation and evaluation of the application. The reporting Member State shall consult and coordinate with the other concerned Member States. Ethics Committee (similar to an Investigational Review Board) review of the CTA is part of the process under the CTR. If an approval is issued, the sponsor can start the clinical trial in all concerned Member States. However, a concerned Member State can in limited circumstances declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that concerned Member State. The CTR also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

Under the CTR, clinical trial sponsors were able to, but not obligated to, use the CTIS starting January 31, 2022. Beginning January 31, 2023, clinical trial sponsors were required to use the CTIS to submit a CTA for a new clinical trial in the EU or EEA, but clinical trials already approved under the previous law, the Clinical Trials Directive (CTD) can continue running under the CTD until January 31, 2025, at which time the sponsor must comply with the CTR and record information on these studies in the CTIS. National regulators in the EU Member States and EEA countries began to carry out their legal responsibilities in evaluating and overseeing clinical trials using the CTIS beginning January 31, 2022.

Under EU regulatory systems, a company may submit Marketing Authorization Applications (MAA) under national, centralized or decentralized, or mutual-recognition procedures. We expect to utilize the centralized procedure, which is compulsory for medicinal

products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the EMA, where it is 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 EC of a single marketing authorization that is valid for all EU member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

Conditional marketing authorization in the EU 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. A different marketing authorization pathway is also available to sponsors, called "exceptional circumstances" under which the EC grants marketing authorization of a product for a specific condition or disease when comprehensive data cannot be obtained even after authorization (e.g., for rare conditions or diseases). Sponsors who obtain marketing authorization for a drug product under exceptional circumstances are subject to ongoing post-marketing obligations to continue confirmation of the benefits of the product. Continuation of a marketing authorization granted under the "exceptional circumstances" regulatory pathway is subject to annual re-assessments. The annual re-assessment will determine whether the marketing authorization should be maintained, changed, or suspended, based on a sponsor's fulfillment of its post-marketing obligations and the risk/benefit profile of product.

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

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

Outside the U.S., there are additional challenges in ensuring adequate coverage and payment for our products. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory approval for a product and may require us to conduct a clinical study that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of this type of clinical study could be expensive and result in delays to our or our commercialization partners' 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 EU 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 with price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

The EC is currently conducting a wholesale review of the pharmaceutical legal framework, which includes the regulatory protection afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extension. It is expected that the protection currently afforded in the EU will be reduced in the years to come and the new EU

legislative proposal is expected to be published by the EC in the second quarter of 2023, although this timeline may be further prolonged.

Brexit and the Regulatory Framework in the United Kingdom

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

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, UK Legislation has retained existing EU law. However, new UK legislation is being drafted and the UK has not implemented new EU law, such as the CTR; therefore Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK and the EU. Great Britain (made up of England, Scotland and Wales) is no longer covered by the EEA's procedures for the grant of marketing authorizations (Northern Ireland will be covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures, as the EU legal framework continues to apply in Northern Ireland, under the Northern Ireland Protocol). A separate marketing authorization will be required to market drugs in Great Britain. It is currently unclear whether the Medical Healthcare products Regulatory Agency (MHRA) in the United Kingdom is sufficiently prepared to handle the increased volume of MAAs that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, would delay or prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

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

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

Additional Regulation

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by, our operations. Our research and development involve 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 April 2022, we sold all of our right, title and interest in and to certain assets related to the Atara T-Cell Operations and Manufacturing facility (ATOM Facility) located in Thousand Oaks, California to FDB. We also entered into a Master Services and Supply Agreement with FDB (Fujifilm MSA) which became effective in April 2022 and could extend for up to ten years. Pursuant to

the Fujifilm MSA, FDB will supply us with specified quantities of our product and product candidates, manufactured in accordance with cGMP standards. The Fujifilm MSA does not obligate us to purchase our product and product candidates exclusively from FDB.

We continue to scale our EBV T-cell manufacturing platform to improve product yields from a single donor leukapheresis collection and have generated data confirming the use of stirred-tank bioreactors to improve yield and cell growth productivity. We believe our scalable technology can potentially be a key enabler to deliver biologic-like cost of goods manufactured and could be leveraged across our portfolio, including our CAR T programs.

In addition to FDB, we also work with Charles River Laboratories Inc. (CRL) pursuant to a Commercial Manufacturing Services Agreement (CRL MSA) that we entered into in December 2019. Pursuant to the CRL MSA, CRL provides manufacturing services for our product and certain intermediates. We further amended the CRL MSA to extend the term until the earlier of March 31, 2024 or upon receipt of certain batches of our product and intermediates. We are currently in negotiations with CRL for a new commercial drug product supply agreement to be effective upon the expiration of the CRL MSA. However, there can be no assurance that we will be able to enter into a new commercial drug product supply agreement with CRL on terms favorable or acceptable to us, or at all. If we are unable to enter into a new commercial drug product supply agreement or extend the CRL MSA, we may need to identify alternative sources of drug product supply.

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

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

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

Human Capital Management

As of December 31, 2023, we had 225 employees, excluding those impacted by the reduction in force in November 2023, which was subsequently reduced by approximately 25% as a result of the January 2024 reduction in force. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. Our human capital strategy is designed to enable successful execution of our business objectives, while fostering a collaborative and innovative culture, that embraces diversity and inclusion. We monitor our success with insights across human capital metrics such as employee engagement, vacancy rates, time to hire, promotion rates, performance ratings, succession depth, retention, EEO compliance, pay equity, and diversity representation. The principal purposes of our compensation policies and equity incentive plans are to attract, retain and motivate employees and directors by paying for performance through the granting of stock-based compensation awards and cash-based performance bonus awards. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we consider our relations with our employees to be good.

COVID-19 Business Update

To date, the COVID-19 pandemic has not materially impacted our or our partners' clinical, research and development, regulatory, and manufacturing operations or timelines. We have transitioned a portion of our workforce to a remote, work-from-home

model, while maintaining essential in-person laboratory functions in order to advance key research, development and manufacturing priorities. We implemented safety protocols and procedures to support our onsite workforce.

The full extent to which the COVID-19 pandemic may impact our business and operations is subject to future developments which are uncertain and difficult to predict.

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

Corporate Information

We were incorporated in Delaware in 2012. Our principal corporate offices are located at 2380 Conejo Spectrum St., Suite 200, Thousand Oaks, California 91320 and our telephone number at that address is (805) 623-4211. Our website address is www.atarabio.com.

Available Information

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

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

Item 1A. Risk Factors

Investing in our 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 financial statements and related notes, before investing in our common stock.

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

Risks Related to Our Financial Results and Capital Needs

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that product candidates will fail to prove effective, gain regulatory approval or become commercially viable. We have one product, Ebvallo, which is approved in the EU and the UK and have generated limited revenues from commercialization, 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 incurred significant operating losses in every annual reporting period since our inception. For the year ended December 31, 2023, we reported a net loss of $276.1 million.

We do not know when, or if, we will generate sufficient revenue from commercialization to offset our operating expenses. We expect to continue to incur significant expenses and operating losses for the foreseeable future 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. 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 change 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. Our expenses may 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.

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 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 3 clinical studies, obtain regulatory approval in the U.S., 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 or arrange for a third party to do so on our behalf. 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 prove to be inaccurate.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. 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 have earned limited commercialization revenues to date. We may never achieve profitability.

To date, we have generated only limited revenues from commercialization. We have regulatory approval for one product, Ebvallo, in the EU and the UK. We have out-licensed the commercialization rights to tab-cel (Ebvallo in the EU and the UK) to Pierre Fabre under the A&R Commercialization Agreement and we have sold certain royalty and milestone interests for the Initial Territory, subject to a specified cap, to HCRx pursuant to the HCRx Agreement. Our ability to generate revenues from commercialization and achieve profitability will be subject to the A&R Commercialization Agreement, the HCRx Agreement and depend on our commercialization partners' ability to successfully commercialize products, including any of our current product and product candidates, and other product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenues from the sale of products and achieve profitability will also depend on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical studies with positive results;
- complete and submit regulatory submissions to the FDA, EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- develop manufacturing and distribution processes for our novel T-cell immunotherapy product candidates;
- develop commercial quantities of our products, including 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 and commercialization relationships with reliable third parties;
- qualify our CMOs' manufacturing facilities 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 and regulatory requirements;
- achieve market acceptance of and pricing and reimbursement for our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property and regulatory protections portfolio; and
- find suitable commercialization partners who can obtain coverage and adequate reimbursement from third parties, including government payors, set commercially viable prices, market, sell and distribute our approved products.

Our revenues from Ebvallo or 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 the terms and conditions of our commercialization agreement with our partner for that territory. We do not retain any meaningful milestones or royalty payments from Pierre Fabre for Ebvallo in the Initial Territory until the applicable royalty cap under the HCRx Agreement is met, which could take many years, if at all. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice, treatment guidelines or a reduction in the incidence of the addressable disease, our partners may not successfully commercialize our products, even if approved. The timing and amount of any milestone and royalty payments we may receive from our partners, as well as the commercial success of our products will depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of our products by our partners. As a result, even if we generate product 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 on terms acceptable to us 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 manufacturing 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 our product and product candidates and the technology we have licensed or have an exclusive right to license from our partners. These expenditures will include costs associated with research and development, potentially acquiring or licensing new product candidates or technologies, conducting preclinical and clinical studies and potentially obtaining regulatory approvals and manufacturing products. Under the terms of our license agreements with each of our in-license partners, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. 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 and product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates, if clinical studies are successful, including any costs from post-market requirements;
- the cost of contracting for the manufacture of our product and 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 product and future products, if any; and
- the emergence of competing technologies or other adverse market developments.

We expect that existing cash, cash equivalents and short-term investments, combined with certain anticipated payments from the A&R Commercialization Agreement, as well as cost reductions from completed workforce reductions and operating efficiencies resulting from our planned transition of substantially all activities relating to tab-cel at the time of the BLA transfer to Pierre Fabre, will enable us to fund our planned operations into 2027. Such anticipated payments are estimates based on assumptions and plans that are subject to change and such changes could materially impact our cash runway. These assumptions include the receipt of future payments that are dependent upon the successful filing and approval of the tab-cel BLA, as well as the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time.

Our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. We do not have any committed external source of funds other than milestone and royalty payments that we may receive under the A&R Commercialization Agreement, subject to the terms of the HCRx Agreement. We do not retain any meaningful milestone or royalty payments related to the Initial Territory from Pierre Fabre until the applicable royalty cap under the HCRx Agreement is met, if at all.

As of December 31, 2023, we had total cash, cash equivalents and short-term investments of $51.7 million. Our existing cash, cash equivalents and short-term investments as of December 31, 2023 will not be sufficient to fund our planned operations for at least the next twelve months from the date of issuance of these financial statements. These conditions raise substantial doubt about our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private security offerings; use of our ATM facility; and/or strategic transactions. We may also need to raise additional funding as required based on the status of our development programs and our projected cash flows. Although we have been successful in raising capital in the past, and expect to continue to raise capital as required, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we are unable to obtain sufficient funding on acceptable terms, we could be forced to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates, which could have a material adverse effect on our business, results of operations, and financial condition.

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 plan to seek required additional capital, and may do so through a variety of means, including through private and public equity offerings and debt financings. For example, in December 2022, we sold certain of our royalty and milestone interests related to the Initial Territory under the amended and restated Pierre Fabre Commercialization Agreement, subject to a specified cap, to HCRx pursuant to the HCRx Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or if existing holders of warrants exercise their rights to purchase common stock, the ownership interest of existing

stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. To the extent equity valuations, including the trading price of our common stock, are depressed as a result of economic disruptions or other uncertainties, for example due to rising inflationary pressures, the war in Ukraine, the war in the Middle East or other factors, the potential magnitude of this dilution will increase. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses or other rights on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop ourselves or take other actions that are adverse to our business.

If we fail to continue to meet the listing standards of Nasdaq, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

Our common stock is currently listed on the Nasdaq Global Market. Nasdaq has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum bid price of $1.00 per share of our common stock (the "Bid Price Requirement"). If the closing bid price of our common stock falls below $1.00 per share for 30 consecutive trading days or we do not meet other listing requirements, we would fail to be in compliance with Nasdaq listing standards. There can be no assurance that we will continue to meet the Bid Price Requirement, or any other requirement in the future.

On January 8, 2024, we received a deficiency letter from the Listing Qualifications Department of Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the Bid Price Requirement.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (Compliance Period Rule), we have been provided a period of 180 calendar days, or until July 8, 2024 (Compliance Date), to regain compliance with the Bid Price Requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, Nasdaq will provide us written communication that we have regained compliance with the Bid Price Requirement.

If we do not regain compliance with the Bid Price Requirement by the Compliance date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we will be required to (i) transfer to the Nasdaq Capital Market, (ii) provide written notice of our intention to cure the deficiency during the additional 180 calendar day compliance period, by effecting a reverse stock split, if necessary, and (iii) and meet the continued listing requirement for market value of its publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Bid Price Requirement, which requirements include, among other things, a minimum stockholders' equity of at least $4 million. For the year ended December 31, 2023, we reported total stockholders' deficit of $99.2 million, which is below the stockholders' equity requirement under the applicable standards.

If we do not regain compliance with the Bid Price Requirement by the Compliance Date and we are not eligible for an additional compliance period, or Nasdaq concludes that we will not be able to cure the deficiency during the additional compliance period, Nasdaq will provide us written notification that our common stock will be subject to delisting. At that time, we may appeal the delisting determination to a Nasdaq Hearings Panel. However, there can be no assurance that such appeal would be successful. If the Nasdaq Hearing Panel does not result in Nasdaq granting us an extension of time to achieve compliance with the Minimum Bid Price Rule, our common stock will be delisted from Nasdaq.

If our common stock were to be delisted, the actual and potential liquidity of our common stock and our ability to raise future capital would be adversely affected and the market price of our common stock could decrease. If, for any reason, we are unable to obtain listing on another national securities exchange or take action to restore our compliance with Nasdaq's continued listing requirements, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our securities;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and

● the number of broker-dealers willing to execute trades in shares of our common stock

Our workforce reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In August 2022, we reduced our workforce by approximately 20% across all areas of our company, including members of management. In November 2023, we further reduced our workforce by approximately 30%. In January 2024, we announced another reduction of our workforce by approximately 25%. The reductions in force reflect a prioritization around key research and development programs and the reduction of our expense profile. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from restructuring, our operating results and financial condition would be adversely affected. We also cannot be certain that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our cost savings plan may be disruptive to our operations, which could affect our ability to generate product revenue. In addition, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future, including tab-cel, if approved.

There can be no assurance that we will achieve all of the anticipated benefits of the Fujifilm Transaction and we could face unanticipated challenges.

We may not realize some or all of the anticipated benefits from the Fujifilm Transaction and we may encounter post-closing risks, including associated with the provision of services to us by FDB pursuant to the Fujifilm MSA. We may experience increased difficulty and loss of institutional knowledge as a result of the transfer of ATOM Facility employees to FDB in connection with the Fujifilm Transaction, which could harm our business. Additionally, significant time and resources may be required from us, which could disrupt our business and distract management from other responsibilities, which may result in losses or continued financial involvement in the ATOM Facility, including through indemnification or other financial arrangements, which could adversely affect our financial results.

Risks Related to the Development of Our Product and Product Candidates

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

We have one approved product, Ebvallo, in the EU and the UK and are generally early in our development efforts, and only a small number of our product candidates are in clinical development. The majority of our product candidates are currently in preclinical development. We have invested substantial resources in identifying and developing potential product candidates, conducting preclinical and clinical studies, manufacturing activities, and preparing for the commercial launch of our product and product candidates. Our ability to generate revenues from the sale of our product and product candidates, if approved, will depend heavily on the successful development, manufacture and our partners' eventual commercialization of our product and product candidates.

The success of our product and product candidates will depend on many factors, including the following:

•completion of preclinical and clinical studies with positive results, including demonstrating the stability, safety, purity, and potency of our product candidates to the satisfaction of the FDA or other regulatory agencies;

•receipt of regulatory approvals from applicable authorities, including required authorizations for clinical trials and marketing authorizations;

•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 successful arrangements with third party manufacturers and commercialization partners;

•qualifying our and our CMOs’ manufacturing facilities for clinical and commercial manufacturing purposes;

•developing manufacturing and distribution processes for our novel T-cell product candidates and next-generation CAR T programs;

•contracting with third parties for the manufacture of our product candidates at an acceptable cost;

•contracting with third parties for commercialization of our products on terms favorable to us, if approved by applicable regulatory authorities;

•acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;

•our partners' ability to obtain and maintain 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 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.

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

Our business could be adversely affected by health epidemics and pandemics, including the COVID-19 pandemic, which presented a substantial public health and economic challenge around the world and has affected, and continues to affect, our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. We continue to maintain essential in-person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. In connection with these measures, we may be subject to claims based upon, arising out of, or related to COVID-19 and our actions and responses thereto. The effects of potential future state executive orders, local shelter-in-place orders, government-imposed quarantines, our work-from-home policies and other similar actions may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Further quarantines, shelter-in-place or similar restrictions and other actions taken by foreign, federal, state and local governments, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could be reinstated, related to COVID-19, other health epidemics and pandemics, or other infectious diseases, could impact our manufacturing capabilities and third party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, standard transportation channels were impacted and may again be impacted, and we and other manufacturing, testing, product disposition, CMOs and external testing laboratories are subject to enhanced risk assessment and mitigation measures. In addition, there were and may continue to be interruptions in the supply of leukapheresis collections, which supply raw materials used in our products.

Our clinical trials may also be affected by health epidemics and pandemics and have been affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment experienced delays as a result of the COVID-19 pandemic, including due to the prioritization of hospital resources toward COVID-19 and away from clinical trials and as a result of changing practice patterns that impact the diseases our trials address. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services or if patients are forced to quarantine due to a health epidemic or pandemic. For example, while most clinical trial sites for our studies, including our Phase 3 clinical trial of tab-cel in patients with EBV+ PTLD, remained open to enrollment for patients, some sites limited the screening and enrollment of new patients due to governmental orders related to COVID-19, or fear of infection of COVID-19, limited, and may limit in the future, patients' abilities to access clinical sites. Pandemic-related travel restrictions may also interrupt key clinical trial activities, such as clinical trial site data monitoring and the collection, processing and analyses of efficacy, safety and translational data. For example, at the outset of the COVID-19 pandemic, we observed a temporary slow-down in stem cell and solid organ transplant volumes, which may have decreased the eligible patient population for the tab-cel Phase 3 study. In April 2020, we initiated a temporary pause in the screening and enrollment of patients in our EMBOLD study of ATA188 in patients with PMS. Although we were able to resume the screening and enrollment of patients in our EMBOLD study and enrolled the first patient in the study in June 2020, the COVID-19 pandemic required us to pause screening and enrollment of patients in our clinical studies. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to health epidemics and pandemics, may be adversely impacted.

In addition, to the extent the COVID-19 pandemic adversely affected our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

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

We only have one product, Ebvallo, that has gained regulatory approval, an approval in the EU and the UK. Currently, our prioritized clinical-stage product candidates include tab-cel (tabelecleucel) in the U.S. and ATA3219 Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to find a partner who can successfully commercialize our product candidates in a timely manner.

Neither we nor our partners can commercialize product candidates in the U.S. without first obtaining regulatory approval for the product candidates from the FDA; similarly, neither we nor our partners can commercialize product candidates outside of the U.S. without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure stability, safety, purity and potency.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical and clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The novel nature of our product candidates may create further challenges in obtaining regulatory approval. For example, the FDA and comparable foreign regulatory authorities have limited experience with regulating the development and commercialization of T-cell immunotherapies, particularly allogeneic T-cell product candidates, and CAR T therapies, including assessing the comparability of different versions of such product candidates. In addition, approval policies, regulations, regulatory positions or the type and amount of clinical and other data necessary to gain approval may change during the course of a product candidate's clinical development and throughout regulatory interactions, and may vary among jurisdictions, particularly for novel therapies. The EC and the MHRA has approved the MAA for Ebvallo as a monotherapy treatment for patients with EBV+ PTLD who have received at least one prior therapy under "exceptional circumstances," which is a pathway under which EC and MHRA grant marketing authorization when "comprehensive data cannot be obtained even after authorization." Under the exceptional circumstances marketing authorization, our commercial partner, Pierre Fabre, is subject to ongoing post-marketing obligations to continue confirmation of the benefits of Ebvallo, and if any of our other product candidates are approved under this pathway, we or our future commercial partners will be subject to this obligation. Continuation of the Ebvallo marketing authorization is subject to annual re-assessment. The annual re-assessment will determine whether the Ebvallo marketing authorization should be maintained, changed, or suspended, based on Pierre Fabre's fulfillment of post-marketing obligations and the risk/benefit profile of Ebvallo. If we, or our commercial partners, do not satisfy the ongoing post-marketing obligations or the EC determines that the risk/benefit profile of Ebvallo is not acceptable, the EC may change or suspend the marketing approval for Ebvallo. We have not obtained regulatory approval for any other 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 to demonstrate the stability, safety, purity and potency of the product candidate;

•failure of clinical sites to conduct the study in accordance with applicable regulatory requirements;

•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;

•inability to reach agreement with the FDA or comparable foreign regulatory authorities on the methodologies for, and assessment of, comparability of different versions of product candidates used in non-pivotal studies, pivotal studies and for intended commercial use;

•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 or inconsistencies in the requested or required methodologies, statistical analyses, specification criteria or regulatory submission requirements for a product candidate, including changes to, or inconsistencies with, applicable industry practice or precedent; or

•changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval or in positions, guidance or feedback communicated by the FDA or comparable foreign regulatory authorities that have a negative impact on the potential approval of a product candidate.

The FDA or a comparable foreign regulatory authority may require information beyond what we plan to provide in or expect to be required for a marketing application, including additional CMC information, preclinical or clinical data to support approval. These requirements may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. For example, at a Type B meeting in February 2022, we were not able to align with the FDA on comparability between tab-cel product versions used in the pivotal ALLELE study and the intended commercial product. The FDA initially recommended we conduct a new clinical trial with the commercial product to address the lack of alignment on comparability and to gain additional clinical experience with the intended commercial product. Throughout 2023, we held a number of meetings with the FDA on clinical aspects and CMC for a potential BLA submission for tab-cel. We recently held a pre-BLA meeting with the FDA that supports our plan to submit the tab-cel BLA in the second quarter of 2024. The FDA may not ultimately accept or approve a BLA submission with the current clinical dataset. In this case, the conduct of an additional clinical trial or trials in the lead indication or completing the ongoing ALLELE study may be necessary to support a BLA submission for tab-cel, which would result in considerable delay to a BLA submission or could lead us not to pursue a BLA submission. Conducting an additional clinical trial, if required, may prove too difficult or too expensive, and the process of designing a clinical trial, enrolling enough patients, and completing treatment and data collection under the protocol could take a significant amount of time, effort, and resources. Even if we complete the clinical trial, the study may not meet its prespecified endpoints, and even if it does, the FDA may still disagree that the clinical trial is sufficient to support submission and approval of a BLA for tab-cel, or may consider that the data, while adequate for BLA submission, can support only a more limited indication than that for which we initially applied.

Our development activities and/or commercialization planning with our partners could be harmed or delayed by governmental or regulatory delays due to a variety of factors. These factors include limitations on the availability of governmental and regulatory agency personnel to review regulatory filings or engage with us (caused by global health concerns or otherwise, including the COVID-19 pandemic); changes to governmental regulatory requirements, policies, guidelines or priorities, reallocation, or availability of government resources; or for other reasons, that may significantly delay the FDA's, or other regulatory agencies', ability to review and process any submissions we have filed or may file or cause other regulatory delays. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, or impact reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to review and process our regulatory submissions in a timely fashion, which could have a material adverse effect on our business. For example, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products inspections of domestic manufacturing facilities through April 2020. On March 18, 2020, the FDA announced its intention to postpone temporarily routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. On July 10, 2020, the FDA announced that it is working toward the goal of restarting on-site inspections it deems to be "mission critical." In May 2021, the FDA updated its guidance, first published in August 2020, clarifying how it intends to conduct inspections during the COVID-19 pandemic, including how it plans to determine which inspections are "mission critical." Additionally, on April 14, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. The FDA has since adjusted its inspection activities in response to the COVID-19 pandemic. On December 29, 2021, the FDA implemented temporary changes to its inspection activities to ensure the safety of its employees and regulated firms. On February 2, 2022, FDA announced that it would resume domestic surveillance inspections across all product areas on February 7, 2022. In July 2022, FDA published draft guidance outlining its policies regarding remote regulatory assessments. On May 11, 2023, the COVID-19 Public Health Emergency (PHE) declared under the Public Health Services (PHS) Act expired. It is unclear how FDA's and other health agencies' policies and guidance will impact any inspections of our facilities or clinical trial sites involved with our clinical studies.

If we do obtain approval for a product candidate marketing application, 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 EC and FDA of autologous CAR T therapies, such as Novartis' Kymriah® and Gilead's Yescarta®, may not be indicative of what these regulators may require for approval of our therapies. We have multiple clinical trials of our product candidates currently ongoing. If an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials, such event could adversely affect our other clinical trials of the same or related product candidates. Moreover, our product candidates may not perform successfully in clinical studies or may be associated with adverse events that distinguish them from those that have previously been approved, such as approved autologous CAR T therapies. For instance, allogeneic product candidates may result in adverse events not experienced with autologous products. Even if a product candidate is approved by the FDA and comparable foreign regulatory authorities, the approval might contain significant limitations related to use 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 in a region or country by the respective regulatory agency.

Our T-cell immunotherapy product and 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 our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.

Our future success is dependent on the successful development and commercialization 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 and product candidates that are bioengineered from donors, represent a new approach to immunotherapy for the treatment of cancer and other diseases, developing and commercializing our product candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of T-cell immunotherapies, particularly allogeneic T-cell products and product candidates;
- developing and deploying consistent and reliable processes for procuring blood from consenting third party donors, isolating T cells from the blood of such donors, activating the isolated T cells against a specific antigen, characterizing and storing the resulting activated T cells for future therapeutic use, selecting and delivering a sufficient supply and breadth of appropriate partially HLA-matched cell line from among the available T-cell lines, and finally infusing these activated T cells into patients;
- utilizing these product candidates in combination with other therapies (e.g., immunomodulatory approaches such as checkpoint inhibitors), which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of our product and each of our product candidates, particularly those that may be unique to our allogeneic T-cell product and 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 products and product candidates in a reliable and consistent manner;
- developing processes for the safe administration of these product and product candidates, including long-term follow-up and registries, for all patients who receive these product candidates;
- establishing or making arrangements with third party manufacturers to manufacture, or manufacturing on our own, product and 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 and 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 favorable terms with commercialization partners that possess appropriate 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 and product candidates.

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

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

The FDA may also modify or enhance trial requirements which may affect enrollment. In August 2023, the FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

Physicians, hospitals and third party payors often are slow to utilize new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training on 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, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors. We do not know whether the clinical studies we may conduct, or clinical studies in progress, will demonstrate adequate efficacy and safety to result in regulatory approval to market any product candidates in any particular jurisdiction.

Tab-cel has been predominantly evaluated in single-center studies under investigator-sponsored investigational new drug (INDs) applications held by MSK and in our Expanded Access Programs, utilizing different response criteria and endpoints from those we have used or may utilize in later clinical studies. These Phase 2 clinical studies with tab-cel also enrolled a heterogeneous group of patients with a variety of EBV-driven malignancies, including EBV+ PTLD after HCT and EBV+ PTLD after SOT. These Phase 2 studies were not prospectively designed to evaluate the efficacy of tab-cel in the treatment of a single disease state for which we may later seek approval. Findings from early studies may not be reproducible in late phase studies we conduct. For instance, the current protocol for our ALLELE study in EBV+ PTLD is designed to rule out a 20% ORR as the null hypothesis. This means that if the lower bound of the 95% confidence interval on ORR among patients receiving at least one dose of tab-cel exceeds 20% at the end of the study, then the study would be expected to meet the primary endpoint for the treatment of PTLD. For example, assuming enrollment of 33 patients in a cohort of ALLELE, an observed ORR above approximately 37% would be expected to meet the primary endpoint for that cohort. In addition, our amended ALLELE study protocol includes an interim analysis as well as a final study analysis. We have previously received feedback from the FDA that an interim analysis of the ALLELE study may not be sufficient to support approval of a BLA. Moreover, final study results may not be consistent with interim study results. Furthermore, modifications to the total sample size of the ALLELE study and the statistical approach may be necessary in connection with the review of such a BLA submission by the FDA.

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

Ebvallo was approved under the exceptional circumstances regulatory pathway by the EMA and the MHRA, therefore continuation of the Ebvallo marketing authorizations in the EU and the UK are subject to annual reassessments. The annual reassessments will determine whether the Ebvallo marketing authorization should be maintained, changed, or suspended, based on Pierre Fabre's fulfillment of post-marketing obligations and the risk/benefit profile of Ebvallo.

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

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

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

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

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

- delays in enrollment due to travel, shelter-in-place or quarantine policies, or other factors, related to the COVID-19 pandemic or other epidemics or pandemics;
- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a study design that we are able to execute;
- delay or failure in obtaining authorization to commence a study or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a study;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical study at each site;
- withdrawal of clinical study sites from our clinical studies or the ineligibility of a site to participate in our clinical studies;
- delay or failure in recruiting and enrolling eligible subjects to participate in a study;
- delay or failure in subjects completing a study or returning for post-treatment follow-up;
- clinical sites and investigators deviating from study protocol, failing to conduct the study in accordance with regulatory requirements, or dropping out of a study;
- an FDA or other regulatory authority clinical site inspection reveals serious violations of regulations applicable to clinical investigations, which may result in requests for additional data analyses and/or rejection of data deemed unreliable;

•inability to identify and maintain a sufficient number of study sites, including because potential study sites may already be engaged in competing clinical study programs enrolling the same population;

•failure of our third-party clinical study managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;

•delay or failure in adding new study sites;

•interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;

•feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol for a study;

•a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical studies for non-compliance with regulatory requirements, safety issues, including a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risk, or for any other reason;

•unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;

•failure to demonstrate a benefit from using a product candidate;

•difficulties in manufacturing or obtaining from third parties sufficient quantities and breadth of appropriate partially HLA matched cell lines from among the available T-cell lines to start or to use in clinical studies;

•lack of adequate funding to continue a study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or

•changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical study.

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

•the size and nature of the patient population;

•the possibility that the rare diseases that many of our product candidates address are under-diagnosed;

•changing medical practice patterns or guidelines related to the diseases or conditions we are investigating;

•the severity of the disease under investigation;

•our ability to open clinical study sites;

•the proximity of subjects to clinical sites;

•the patient referral practices of physicians;

•the design and eligibility criteria of the clinical study;

•ability to obtain and maintain patient consents;

•risk that enrolled subjects will drop out or die before completion;

•competition for patients from other clinical studies;

•our or our partner’s ability to manufacture the requisite materials for a study;

•risk that we do not have appropriately matched HLA cell lines;

•clinicians’ and patients’ perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the diseases or conditions we are investigating; and

•disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic.

As an example, we activated additional clinical sites for the ALLELE study of tab-cel over the course of 2018 and increased HLA coverage during this period. As a result, enrollment in our studies was limited in the early part of 2018 and increased through the course of the year as we increased clinical sites and HLA coverage. However, in May 2019, we announced that enrollment in our Phase 3 studies of tab-cel for patients with EBV+ PTLD was proceeding slower than anticipated. Many of our product candidates are designed to treat rare diseases, and as a result, the pool of potential patients with respect to a given disease is small. We may not be able to initiate or continue to support clinical studies of tab-cel or any other product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies as required by the FDA or other regulatory authorities. We experienced some transient delays in clinical trial site initiation and patient enrollment in certain of our clinical trials, including our ALLELE study, as a result of the COVID-19 pandemic. 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. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Reliance on CROs entails risks to which we would not be subject if we conducted our clinical studies ourselves, including reliance on the CRO for clinical site initiation and monitoring, the possibility that the CRO does not maintain the financial resources to meet its obligations under our agreements, the possibility of breach of these agreements by the CRO because of factors beyond our control, including a failure to properly perform their obligations under these agreements, and the possibility of termination or non-renewal of the agreements by the CROs, based on their own business priorities, at a time that is costly or damaging to us. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan, study protocols for the trial, statistical analysis plan and other study-specific documents (for example, monitoring and blinding plans). Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practice (GCP), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines, and regulations regarding the informed consent process, safety reporting requirements, data collection guidelines, and other regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP and other applicable regulations. In addition, our clinical trials must be conducted with product produced under applicable current Good Manufacturing Practices (cGMP) and current Good Tissue Practices (cGTP) regulations. Our failure to comply with these regulations may require us to conduct new clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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 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 and 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 and product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we or our partners may experience in our clinical studies, we or our partners may not receive approval to market any product candidates, which could prevent us from ever generating product or royalty revenues for such product candidates or achieving profitability. Results of our studies could reveal an unacceptably high severity and incidence of side effects, or risks that outweigh the benefits of our product and 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, IRBs, or other clinical trial oversight bodies may place a hold on any ongoing clinical trials;
- 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;
- our products may be seized, or we may be required to recall our products;
- our products may become less competitive in the marketplace; and
- our reputation may suffer.

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

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

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

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy, and who have the potential to benefit from treatment with our product and product candidates, are based on our current beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinicians, patient foundations, or our own market research, and may prove to be incorrect. Further, new studies, product approvals, changes to the standard of care and diagnosis rates or scientific understanding of disease burden may change the estimated incidence or prevalence of these diseases, and the number of patients who could benefit from our products may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect our product, tab-cel, to initially target a patient population that suffers from aggressive EBV+PTLD and has failed rituximab or rituximab plus chemotherapy. Our commercial partners may have different estimates of the market opportunities for our product or product candidates. At the outset of the COVID-19 pandemic, we initially observed a temporary slow-down in stem cell and solid organ transplant volumes. These reductions were transient, but if a reduction in such volumes resumes or if there are other disruptive factors that reduce PTLD incidence, such as changes in immunosuppression regimens or treatment of re-activated viremia, it could result in lower PTLD incidence and thus reduce the demand for tab-cel. Even if our product and product candidates obtain significant market share, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

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

Regulatory authorities in some jurisdictions, including the U.S., EU and the UK, 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. The FDA, the EMA, and the MHRA have granted us orphan drug designation for tab-cel for EBV+ PTLD.

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 FDA, the EMA, and the MHRA from approving another marketing application for the same biologic for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in the EU and the UK. The EU and UK exclusivity periods 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. These periods may be reduced in the EU based on a new applicable legal framework, currently under review by the European Parliament and Council. Orphan drug exclusivity may be lost if the FDA, EMA or MHRA 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. In the U.S., the FDA may still approve a later marketing application blocked by an ongoing period of orphan drug exclusivity in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was approved. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve or license other drugs or biological products that have a different active ingredient for use in treating the same indication or disease.

In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a 2021 11th Circuit decision, *Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021)*, in which the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease, and not to all uses or indications within the entire disease or condition. In particular, the circuit court held that that the orphan-drug exclusivity for the drug developed by Catalyst Pharmaceuticals, Inc. (Catalyst) blocked the FDA's approval of another drug for all uses or indications within the same orphan-designated disease, Lambert-Eaton myasthenic syndrome (LEMS), even though Catalyst's drug was approved at that time only for use in the treatment of LEMS in adults. Accordingly, the court ordered the FDA to set aside the approval of a drug indicated for LEMS in children. This decision created uncertainty in the application of the orphan drug exclusivity. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and could materially adversely affect our business, financial condition, results of operations, cash flows and prospect.

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.

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

Although we have obtained BTD for tab-cel in the U.S. for treatment of patients with EBV+ PTLD who have failed rituximab, these designations 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 other expedited review programs, such as priority review. Based on our BTD, we may pursue a rolling submission strategy for our BLA for tab-cel for EBV+ PTLD in the U.S. While a rolling review process may provide the opportunity for ongoing communications with and feedback from the FDA, it may not result in a faster timeline to marketing approval and has no bearing on whether or not tab-cel is ultimately approved. The FDA may raise issues and pose questions to us that may delay the initiation and completion of our BLA submission, acceptance of the complete BLA for filing, and approval of the BLA. We may not be able to provide a satisfactory or a timely response to FDA questions or we may not be able to gather the required data to prepare our BLA submissions as we plan. If we are unable to address all questions or concerns that the FDA may raise or if we do not have timely access to the data required for the preparation of the BLA, we may not be able to initiate and complete our BLA in a timely manner and ultimately receive FDA approval. In addition, even if we submit our BLA under the rolling review process, the FDA may decide not to review portions of our BLA under the rolling review process until the submission is deemed to be complete.

PRIME designation supports the development and accelerated review by the EMA of new therapies to treat patients with unmet medical need. Despite this designation and the associated opportunity for accelerated assessment, the EMA may decide that additional time is needed for the MAA review and convert the MAA to a standard review timeline. For example, the EMA converted the tab-cel MAA review timeline from accelerated to standard.

Designation as a breakthrough therapy is at the discretion of the FDA, and access to PRIME is at the discretion of the EMA. Receipt of a BTD or PRIME designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA or EMA review procedures and does not assure ultimate approval by either the FDA or EMA. In addition, the FDA or EMA, respectively, may later decide that the product no longer meets the conditions for qualification and rescind the BTD or PRIME designation or decide that the time period for FDA or EMA, respectively, review or approval will not be shortened. For example, in June 2022, FDA published a draft guidance document outlining considerations for the FDA in rescinding BTD for products that no longer meet the requirements for that designation.

A Fast Track designation by the FDA, even if granted for other current or future product candidates, may not lead to a faster development or regulatory review, licensure process and does not increase the likelihood that our product candidates will receive marketing licensure.

We may seek fast track designation for one or more of our future product candidates. If a drug or biological product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA fast track designation for a particular indication. We may seek fast track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates. Marketing applications submitted by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing licensure by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways and receiving a fast track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw fast track designation at any time, including if it believes that the designation is no longer supported by data from our clinical development program.

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

In addition to regulations in the U.S., to market and sell our products in the EU, the UK, many Asian countries and other jurisdictions, we, or our current or future commercialization partners, 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 and may include additional risks. 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 or our partners 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 a regulatory agency or payor does not ensure approval by any other regulatory or payor authorities in other countries or jurisdictions. 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 or our partners are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the US, EU, the UK, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished.

The proposed revision of the European legislation on pharmaceuticals could lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU, including orphan medicinal products.

In April 2023, the EC published proposals to revise the existing European legislation on medicinal products (EU Pharma Law Review). The revisions consist of two proposals, a new directive and a new regulation (EU Pharma Law Proposal) that would amend and/or repeal and replace the relevant legislation concerning medicinal products for human use, including legislation concerning orphan medicinal products and medicinal products for pediatric use. The EU pharma Law Review could have a significant impact on the designation of and incentives offered to orphan medicinal products in the EU. If adopted in current form, the EU Pharma Law Proposal would introduce the possibility for the Commission, by way of delegated acts, to derogate from the current prevalence criterion, and introduce specific criteria for certain conditions, due to the characteristics of such conditions or other scientific reasons. The EU Pharma Law Proposal also proposes changes to the current orphan market exclusivity (OME) approach. If adopted in the

current form, the EU Pharma Law Proposal would in most cases reduce the duration of the OME and replace the current system of separate OME periods for each new indication with a system with a single OME period for each active substance.

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

Even if we, or our partners 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 CMOs and CROs for any post-approval clinical studies that we conduct. They also include any post-approval requirements or commitments imposed by FDA or comparable foreign regulatory authorities as a condition of approval, or any risk evaluation or mitigation strategies (REMS), if applicable. 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 cGMP, current GCP, current 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 products, product candidates, or the manufacturing facilities for our products or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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

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

comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

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

Changes to regulations, recommendations or other guidelines advocating alternative therapies for the indications we treat could result in decreased use of our products. For example, although treatment with EBV-specific T cells is recognized as a recommended treatment for persistent or progressive EBV+ PTLD as set forth in the 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 to develop 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 internal development, 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. Any product candidates we identify, acquire, in-license, develop, or manufacture may not be safe or effective for their targeted diseases, and may not receive marketing authorization in a timely manner, or at all.

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 and product candidates.

Concurrently with the in-license of our existing product and product candidates, we acquired manufacturing process know-how and, in some cases, inventory of process intermediates and clinical materials from our partners. Transferring manufacturing processes, testing and associated know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes and/or equipment 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 and product candidates for various studies, clinical studies and commercial launch readiness. To the extent we elect to transfer manufacturing within our network of third party CMOs, 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 or availability of additional commercial product supplies.

The processes by which some of our product and product candidates are manufactured were initially developed by our partners for clinical purposes. We intend to evolve the processes developed by our partners and the processes developed by us to support advanced clinical studies and commercialization requirements. We similarly intend to evolve the processes originating at Atara 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, comparability issues, stability, safety, purity and potency issues, regulatory agency review and endorsement processes, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product and product candidates will be made could be adversely affected by pandemics, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors. In addition, there have been, and there may continue to be, transient interruptions in the supply of raw materials and consumables used in the development and manufacturing of our preclinical and clinical cell therapies related to raw material shortages due to the COVID-19 pandemic or other global pressures, including leukapheresis collections, which supply starting materials used in our product and product candidates, and raw materials and consumables specialized for cell therapy manufacturing. If we are unable to obtain such raw materials or other necessary raw materials in a timely manner, our business operations and manufacturing capabilities could be adversely affected.

The process of manufacturing cellular therapies is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product and 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 contamination is discovered in reagents or in our product and product candidates or in the manufacturing facilities in which our product and 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. For example, we were informed by a CMO of mold contamination in certain manufacturing suites related to the manufacture of finished Ebvallo and tab-cel product and intermediates at the CMO's facility and we worked with the CMO to investigate and remediate such contamination issue while production continued in other manufacturing suites. Because our T-cell immunotherapy product and product candidates are manufactured from cells collected 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 and product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product and 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. Viral contaminants may also arise in recombinant viral reagent production systems used to manufacture viral reagents used to manufacture product and product candidates. These types 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 intermediate or cell product lots, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell product lot for therapeutic use in a patient requires close coordination between clinical operations, supply chain and quality assurance personnel.

Any adverse developments affecting our, or our CMOs' manufacturing operations for our product and 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 or our ability to supply product to our commercial partners, including Pierre Fabre. 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 and 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.

Delays in receiving regulatory approvals for product candidates produced at our CMOs' facilities could delay our development plans and thereby limit our ability to generate revenues.

The research and development and process and analytical development labs within ARC and our facility in Aurora, Colorado, currently support our preclinical and mid/late development activities. Product-specific qualification to support clinical development and commercial production qualification activities are ongoing for product candidates at our CMOs' facilities. If the appropriate regulatory approvals for manufacturing product candidates at our CMOs' facilities are delayed, we may not be able to manufacture sufficient quantities of our product candidates, which would limit our development activities and our opportunities for growth.

In addition to the similar manufacturing risks described in "Risks Related to Our Dependence on Third Parties," our facilities, and our CMOs' facilities, will be subject to ongoing, periodic inspection by the FDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP and GTP. Our, or our partner's, failure to follow and document 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 inventory of 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
- achieving and maintaining ongoing compliance with cGMP regulations and other requirements of the FDA, EMA or other comparable regulatory agencies.

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

Developing advanced manufacturing techniques and process controls is costly, time consuming and is required to fully utilize our or our CMOs' facilities. Failure to advance manufacturing techniques and process controls could lead to a delay in obtaining approval for our product candidates. Without further investment, advances in manufacturing techniques may render the facilities and equipment that manufacture our product candidates 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 sufficient quantities to meet future demand.

If one or more of our CMO's facilities is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.

If any of our CMOs' manufacturing facilities, or the equipment in any such facilities, is either damaged or destroyed, we may not be able to quickly or inexpensively replace such manufacturing capacity or replace it at all. In the event of a temporary or protracted disruption in operations or loss of a facility or its equipment, we may not be able to transfer manufacturing to another third party in the time required to maintain supply. Even if we could transfer manufacturing to another 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 revenues.

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 or CMOs we may delay development and/or commercialization of our product and product candidates.

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

To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tab-cel, 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. 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, analytical methods 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 us or our CMOs.

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

We still may need to identify additional CMOs for continued production of supply for some of our product and 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, and the critical intermediates or reagents used to manufacture such products, are 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.

We rely on our CMOs and manufacturing network for the production of our product and product candidates. Our supply, and ability to maintain inventory, of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, failure to meet regulatory or cGMP requirements, labor or raw material shortages, public health epidemics, natural disasters, power failures, cyber-attacks and many other factors. If we encounter any manufacturing or supply chain difficulties, we may be unable to meet the demand for our products and product candidates.

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 and analytical methods to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product, product candidate or intermediate would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our product and 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 methodologies or assessments for these materials, regulatory authorities may require that we conduct additional studies, including bridging comparability testing, and further clinical development or commercial launch of our product candidates could be substantially delayed.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product and 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 or our partners may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, the possibility that the third party does not devote sufficient time or resources to our product candidates or any products we or our partners may eventually commercialize based on its own business priorities, the possibility that the third party is acquired by another party and changes its business priorities, 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. For example, the CRL MSA expires on March 31, 2024. While we are in active negotiations with CRL for a new commercial manufacturing agreement, there can be no assurance that we will be able to enter into a new commercial drug product supply agreement with CRL on terms favorable or acceptable to us or at all. Any delays in entering into a new commercial manufacturing agreement and/or further extension of the current CRL MSA could delay the development and commercialization of our product and product candidates, if approved. In addition, if we are unable enter into a new commercial manufacturing agreement with CRL on acceptable terms, or at all, we would have to explore other options for the manufacture of our product and product candidates, which could harm our business. If Fujifilm does not perform its obligations under the Fujifilm MSA adequately or does not devote sufficient time or resources to our product or product candidates, our operations, including the commercialization of our products, may be adversely impacted. Similarly, if CRL does not perform its obligations under the CRL MSA adequately or does not devote sufficient time or resources to our product or product candidates, our operations, including the commercialization of our products, may be adversely impacted. We also have non-cancellable minimum purchase commitments for products and services in certain of our agreements with our CMOs, if we do not fulfill such minimum purchase commitments, we will need to pay such CMOs the difference between the applicable minimum purchase commitment and our actual purchases of products and services for a given period. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we or our partners 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 and testing laboratories for key materials used to produce or test our product and 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 and 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 and product candidates.

We are dependent on Pierre Fabre for the commercialization of tab-cel (Ebvallo in the EU, UK) worldwide, including the United States. The failure of Pierre Fabre to meet its contractual, regulatory or other obligations could adversely affect our business and our obligations under the HCRx Agreement.

We have entered into the A&R Commercialization Agreement for tab-cel (Ebvallo in the EU and the UK) worldwide for EBV-positive cancers and are in the process of negotiating amendments to certain ancillary agreements as contemplated by the A&R Commercialization Agreement to further advance our partnership with Pierre Fabre. The closing of the A&R Commercialization Agreement occurred in December 2023. As a result, we are entirely dependent on Pierre Fabre for marketing and commercialization, including negotiation of pricing and reimbursement, of tab-cel. The timing and amount of any milestone and royalty payments we may receive under the A&R Commercialization Agreement, as well as the commercial success of tab-cel, will depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of tab-cel by Pierre Fabre.

Under the terms of the A&R Commercialization Agreement, if we receive US BLA approval for tab-cel in patients with EBV+ PTLD, we are required to transfer the BLA to Pierre Fabre. Pierre Fabre will be responsible for obtaining all other regulatory approvals and maintaining all regulatory approvals. We will depend on Pierre Fabre to comply with numerous and varying regulatory requirements governing, if and when applicable, 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. We do not control the individual efforts of Pierre Fabre and have limited ability to terminate the A&R Commercialization Agreement if Pierre Fabre does not perform as expected. The failure of Pierre Fabre to devote sufficient time and effort to comply with regulatory requirements and maintain the US BLA (if approved), the EU and UK marketing authorizations and other regulatory approvals and/or to meet their obligations to us, could have an adverse impact on our financial results and operations, and our obligations under the HCRx Agreement with respect to the Initial Territory.

We also depend on Pierre Fabre to comply with all applicable laws relative to the commercialization of tab-cel in the Additional Territory. The failure of Pierre Fabre to devote sufficient time and effort to the commercialization of tab-cel; to meet their obligations to us, including for future royalty and milestone payments; to adequately deploy business continuity plans in the event of a crisis; and/or to satisfactorily resolve significant disagreements with us or address other factors could have an adverse impact on our financial results and operations. In addition, if Pierre Fabre violates, or are alleged to have violated, any laws or regulations during the performance of their obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

Any termination, breach or expiration of the A&R Commercialization Agreement or ancillary agreements, could have a material adverse effect on our financial position, and our obligations under the HCRx Agreement with respect to the Initial Territory, by reducing or eliminating our right to receive fees, milestones and royalties. In such an event, we may be required to devote additional efforts and to incur additional costs associated with the transfer of regulatory approvals and commercialization of tab-cel. Alternatively, we may attempt to identify and transact with a new commercialization partner, but there can be no assurance that we would be able to identify a suitable partner or transact on terms similar to the A&R Commercialization Agreement or that are favorable to us.

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

We may desire to form additional strategic alliances, commercialization partnerships, 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. In addition, any termination of established strategic alliance agreements will terminate any potential future funding we may receive under the relevant agreements, and we would have to seek a new partner for development or commercialization, curtail or abandon that development or commercialization, or undertake and fund the development and commercialization of the relevant product. If we seek a new partner but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of products ourselves, we would have to explore other strategic options, including curtailing or abandoning that development or commercialization, which could harm our business. For example, effective July 31, 2022, we terminated the agreements with Bayer pursuant to the Termination, Amendment and Program Transfer Agreement (Bayer Termination Agreement).

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 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, product 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, product candidates and platform technology we have licensed from our partners are protected primarily by patent or patent applications of our partners that we have licensed and as confidential know-how and trade secrets. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

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

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product and 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 and 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 and 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 and 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 and product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product and product candidates are threatened, it could jeopardize our ability to commercialize our product and 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 and 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 and 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 or 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 and product candidates under patent protection, if approved, could be reduced. Even if patents covering our product and 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 or our partners' 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 and product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product and 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 and product candidates that we failed to identify. For example, patent applications covering our product and 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 and 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 and 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, 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 or 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 or product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us.

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

Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product, 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 and 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 or our partners from developing or commercializing a product or 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 and 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 and 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 and QIMR Berghofer that are important to our business. Our discovery and development platform is built, in part, around patent rights in-licensed from our partners. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners would materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product and product candidates and our, or our partners' ability to commercialize the affected product and product candidates. Furthermore, a disagreement under any of these license agreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business.

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

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

Interference or derivation proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non-U.S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, *inter partes* review, post-grant review or other pre-issuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product and 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 and 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, CMOs, 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 and Product Candidates

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

Even if we or our partners 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 and 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;
- the inclusion into clinical treatment guidelines;
- acceptance by physicians and patients of the drug as a safe and effective treatment;
- the administrative and logistical burden of treating patients;
- the ability to identify in a timely manner the appropriate patients who will benefit from specific therapy;
- the consideration 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 and product candidates;

•the cost of treatment in relation to alternative treatments;

•the availability of coverage and adequate reimbursement from, and our commercialization partners' ability to negotiate pricing with, third-party payors and government authorities;

•relative convenience and ease of administration;

•the ability to achieve a pricing and reimbursement recommendation or commercial agreement with national payors; and

•the effectiveness of our commercialization partners' sales and marketing efforts.

Even if we or our partners are able to commercialize our product and 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 our partners 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 continue to support initiatives 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 our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. In some countries such as the U.S., greater cost-shifting from the payor to the patient is also a trend, and higher patient copayments or other administrative burdens could lead to reduced demand from patients or healthcare professionals. This could particularly be the case in a challenging economic climate. Coverage and reimbursement may impact the demand for, or the price of, any product or product candidate for which we obtain regulatory approval, and ultimately our partners' ability to successfully commercialize any product or product candidate for which we obtain regulatory approval.

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

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

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 and 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 (ACA), was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013. As a result of the COVID-19 pandemic, this reduction was temporarily suspended from May 1, 2020 through March 31, 2022, with subsequent reductions to 1% from April 1, 2022 until June 30, 2022. The 2% reduction was then reinstated and has been in effect since June 30, 2022, and will remain in effect (with additional reductions of 2.25% in the first half of 2030 and 3% in the second half of 2030 to offset the COVID-19 suspension) until 2031 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been judicial and Congressional challenges to numerous elements of the ACA, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the ACA. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and eliminating the implementation of certain mandated fees. On June 17, 2021, the U.S. Supreme Court dismissed a legal challenge to the law brought by several states arguing that, without the individual mandate, the entire ACA was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments. Further, the IRA, signed into law in August 2022, extended the provision of enhanced subsidies for individuals purchasing health coverage through the ACA marketplace. The enhanced subsidies, which were originally passed as part of the American Rescue Plan Act are now extended through 2025. In the future, there may be additional challenges and/or amendments to the ACA. It is unclear how future litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product and 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.

For example, in April 2023, the European Commission adopted a wide-ranging proposal for a new Directive and a new Regulation. If made into law, this proposal will revise and replace the existing general pharmaceutical legislation. This change will likely result in significant changes to the pharmaceutical industry. In particular, it is expected that the new Directive and Regulations will, if made into law, affect the duration of the period of regulatory protection afforded to medicinal products including regulatory data protection (also called "data exclusivity"), marketing exclusivity afforded to orphan medicinal products, as well as the conditions of eligibility to the orphan designation.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the U.S. or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of

our product and product candidates, if any, may be. In the U.S., the EU and other potentially significant markets for our product and product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. In the U.S., there have been several 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. For example, the Consolidated Appropriations Act of 2021 included several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of Health and Human Services, Labor, and the Treasury. Additionally, the IRA allows Medicare to: beginning in 2026, establish a "maximum fair price" for certain pharmaceutical and biological products covered under Medicare Parts B and D; beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation; and beginning in 2025 impose new discount obligations on pharmaceutical and biological manufacturers for products covered under Medicare Part D. CMS has also taken steps to implement the IRA, including: on June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; on August 29, 2023, releasing the initial list of ten drugs subject to price negotiations; on November 17, 2023, releasing guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase-in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and on December 14, 2023, releasing a list of 48 Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of January 1, 2024 to March 31, 2024. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services, the Secretary of the U.S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions.

There have also been administrative developments in the U.S. related to drug pricing. For example, on February 2, 2022, the Biden Administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting-edge cancer therapeutics and investing in a robust pipeline for new treatments. On September 12, 2022, President Biden issued an Executive Order to promote biotechnology and biomanufacturing innovation. The Order noted several methods through which the Biden Administration would support the advancement of biotechnology and biomanufacturing in healthcare, and instructed the Department of Health and Human Service to submit, within 180 days of the Order, a report assessing how to use biotechnology and biomanufacturing to achieve medical breakthroughs, reduce the overall burden of disease, and improve health outcomes. On October 14, 2022 President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. The Executive Order further directed the Secretary of the Department of Health and Human Services to submit, within 90 days of the date of the Executive Order, a report regarding any models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care. Most recently, on February 14, 2023, the Department of Health and Human Services issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements for certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. On August 29, 2023, CMS released an initial list of ten drugs subject to price negotiations. This negotiation process will occur during 2023 and 2024 and result in maximum prices that will be effective beginning in 2026. While it remains to be seen how the drug pricing provisions imposed by the Inflation Reduction Act (IRA) will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services, the Secretary of the U.S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions.

Other proposed administrative actions may affect our government pricing responsibilities. For example, CMS has issued proposals to amend the existing Medicaid Drug Rebate Program regulations. In addition, there are pending legal and legislative developments relating to the 340B drug pricing program, including ongoing litigation challenging federal enforcement actions against manufacturers and recently introduced and enacted state legislation. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

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. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost". Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the EU 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, other insurers, 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 product and product candidates. If third party payors do not consider our product and product candidates to be cost-effective compared to other therapies, the payors may not cover our product and product candidates after approval 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 EU and the UK, 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 EU 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 and 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 and 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 and 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 and product candidates.

There are currently no FDA-approved products for the treatment of EBV+ PTLD, and there are no EC-approved products for this indication except for Ebvallo. However, we are aware some marketed products and therapies are used per global physician treatment guidelines in the US and the EU in the treatment of EBV+ PTLD by some healthcare professionals and institutions, such as rituximab and combination chemotherapy regimens. In addition, a number of companies and academic institutions are developing product candidates for EBV+ PTLD and other EBV-driven diseases, for example, Viracta Therapeutics, Inc., which is conducting a pivotal, Phase 2 clinical study for nanatinostat (formerly named tractinostat, or VRx-3996) in combination with antiviral drug valganciclovir in relapsed/refractory EBV+ lymphomas.

There are currently six autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel), Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus™ (brexucabtagene autoleucel) and Bristol-Myers Squibb's Breyanzi® (lisocabtagene maraleucel) and Abecma (idecabtagene vicleucel) with 2seventy bio, Johnson & Johnson and Legend Biotech's Carvykti™ (ciltacabtagene autoleucel). There are many CAR-mediated cell therapies in development, and, although the majority are autologous, they also include allogeneic and off-the-shelf cell therapies. There are multiple allogeneic CAR platforms being developed with differences in approaches to minimize instances of donor cells recognizing the patient's body as foreign or rejection of the donor cells by the patient's body. These approaches include the use of gene-editing to remove or inhibit the TCR and the use of cell types

without a TCR. The majority of clinical stage allogeneic CAR programs utilize alpha beta T cells as the cell type and gene editing of the T-cell receptor and HLA as the preferred technology approach, however, other strategies are also in development such as Gamma Delta T cells and NK cells. It is possible that some of these other approaches will have more favorable characteristics than the approach we utilize, which would result in them being favored by potential partners or customers over our products. Depending on the diseases (such as autoimmune diseases) that we target in the future, we may face competition from both autologous and allogeneic CAR therapies and other modalities (e.g., small molecules, antibodies, bispecifics) in the indication of interest.

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

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

We are subject to certain contractual obligations under our royalty financing agreement with HealthCare Royalty Partners and may be subject to claims for damages if we fail to fulfill these obligations.

In December 2022, we entered into a purchase and sale agreement (the HCRx Agreement) with HCR Molag Fund, L.P. (HCRx). Under the terms of the HCRx Agreement, we received $31.0 million in cash in consideration for our right to receive a portion of future royalty payments and certain milestones for Ebvallo in the Initial Territory due to us from Pierre Fabre under the A&R Commercialization Agreement. The HCRx Agreement contains certain customary terms and conditions, including representations and warranties, covenants, and indemnification obligations in favor of each party. Among these terms, there are certain covenants regarding our compliance with the A&R Commercialization Agreement. In the event of actual or alleged breaches of the A&R Commercialization Agreement or the HCRx Agreement, we could be subject to claims for damages from HCRx and could be subject to costly litigation.

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

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. 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 our product and any of the product candidates we develop that are 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 enter into agreements with third parties to market and sell our product and product candidates, we may be unable to generate any revenue from the sale of our products.

In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must enter into agreements with third parties to market and sell our product. There is no guarantee that we will be able to enter into such agreements with third parties or to do so on commercially reasonable terms or in a timely manner. Any failure or delay in entering into agreements with third parties to market and sell our products, would adversely impact the commercialization of these products. There can be no assurance that we would be able to identify a suitable third party to market and sell our product or agree upon terms with third parties that are favorable or acceptable to us, or at all. If we are unable to identify and reach agreement with a third party to market and commercialize our product, we may need to explore other strategic options, including commercializing products ourselves, and there is no guarantee we can successfully commercialize products ourselves. We may be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without a sufficiently scaled, appropriately timed and trained third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

We may encounter difficulties in managing our growth, including with respect to our employee base, and managing our operations successfully.

As of December 31, 2023, we had 225 employees, excluding those impacted by the reduction in force announced in November 2023. In January 2024, we announced another reduction of our workforce by approximately 25%. We may encounter difficulties in managing the size of our operations to support our continuing development activities and the commercialization of our product and potential commercialization of our product candidates by our partners. As our development and commercialization plans and strategies continue to evolve, or as a result of any future acquisitions, we must continue to improve our managerial, operational, financial and other procedures and processes to manage the size our of operations. Our management, personnel and systems currently in place may not be adequate to support any future growth. Future growth would impose significant added responsibilities on members of management, including:

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

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

Risks Related to Ownership of Our Common Stock

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

Our stock price has fluctuated in the past and can be expected to be volatile in the future. From January 1, 2022 through December 31, 2023, the reported sale price of our common stock has fluctuated between $0.20 and $16.93 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In particular, during the COVID-19 pandemic the volatility of the stock market for biopharmaceutical companies was heightened. As a result of the general volatility of the biopharmaceutical market, 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;
- announcements of the results, including safety and efficacy of our product candidates, or progress of our clinical studies;
- results of clinical studies, including safety and efficacy, of our product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent or unusual trading volume levels of our shares or derivatives thereof;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other risks described in this "Risk Factors" section.

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

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

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

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

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

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

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

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

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

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

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock in one or more

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

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

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

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

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

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

Our Bylaws designate a state or federal court located within the State of Delaware as the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our current or former directors, officers, stockholders, or other employees.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, or other employee of the Company to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, or other employees arising pursuant to any provision of the DGCL or our Certificate of Incorporation or Bylaws (as either may be amended

from time to time), (iv) any action asserting a claim against us governed by the internal affairs doctrine, or (v) any other action asserting an "internal corporate claim," as defined under Section 115 of the DGCL. The forgoing provisions do not apply to any claims arising under the Securities Act and, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our current or former directors, officers, or other employees, which may discourage lawsuits with respect to such claims. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find the choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

We recently qualified as a "smaller reporting company" and a "non-accelerated filer," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to such companies could make our common shares less attractive to investors.

As a result of our public float (the market value of our common shares held by non-affiliates) as of June 30, 2023, we qualify as a "smaller reporting company," as defined under the Exchange Act. In addition, we are a "non-accelerated filer" as defined under the Exchange Act. For as long as we continue to be a smaller reporting company or a non-accelerated filer, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies or non-accelerated filers, as applicable, including, but not limited to, an exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act.

If we choose to rely on any of these reporting and disclosure exemptions, the information we provide stockholders will be different than the information that is available with respect to many other public companies. Moreover, if some investors find our common stock less attractive as a result of any choices to reduce future disclosure or have an independent review and attestation of our internal control over financial reporting, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

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 inaccurate or unfavorable research about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

General Risk Factors

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

We are highly dependent upon our executive officers and other key employees and the loss of the services of any of our executive officers or other key employees, including scientific, technical or management personnel, could impede the achievement of our corporate objectives. In August 2022, we announced a reduction of our workforce by approximately 20% across all areas of our company, including members of management. In November 2023, we implemented a further reduction of our workforce by approximately 30%, and in January 2024, we announced an additional reduction of our workforce by approximately 25%, including a member of management. Losing members of management and other key personnel subjects us to a number of risks, including the failure to coordinate responsibilities and tasks, the necessity to create new management systems and processes, the impact on corporate culture, and the retention of historical knowledge.

Our success depends on our ability to recruit, retain, manage and motivate our employees. Although we enter into employment agreements or offer letters with our employees, these documents provide for "at-will" employment, which means that any of our employees could leave our employment at any time, with or without notice. Competition for skilled personnel in our industry and geographic regions is intense and may limit our ability to hire and retain qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity awards that vest

over time. The value to employees of equity awards may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies.

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

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

- the federal healthcare Anti-Kickback Statute, a criminal law that governs, for example, 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;

- the FDCA and PHSA, which prohibit the misbranding and adulteration of biological products that are regulated as drugs, and which regulate the marketing of biological products;

- federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- provisions enacted under the federal HIPAA impose criminal and civil liability for knowingly and willfully executing or attempting to execute, a scheme or artifice to defraud any healthcare benefit program and also impose criminal liability for, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by HITECH also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information;

- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives and U.S. teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;

- state and foreign laws and regulations that are analogous to, and may be broader in scope than, the federal laws and regulations described in this risk factor, such as state anti-kickback and false claims laws, may apply to sales or marketing or other arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; and

•state laws that 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 as well as those that require the registration of pharmaceutical sales representatives; and some 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, reputational harm, contractual damages, and diminished profits and future earnings, any of which could adversely affect our ability to operate our business and our results of operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

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

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

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

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

•decreased demand for any product candidates or products that we may develop;

•clinical holds or 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. As deemed necessary, we may expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

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

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

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

For example, the EU General Data Protection Regulation (EU) 2016/679 (EU GDPR) imposes strict requirements on in-scope organizations regarding the processing of personal information (i.e., data which identifies an individual or from which an individual is identifiable) of individuals (or data subjects). The EU GDPR governs the collection, use, disclosure, transfer and other processing of personal information and has direct effect in all EU Member States and extraterritorial effect where organizations outside of the European Economic Area (EEA) process personal information of individuals in the EEA in relation to the offering of goods or services to those individuals or the monitoring of their behavior. The UK has implemented the EU GDPR into its national law by virtue of section 3 of the European Union (Withdrawal) Act as the UK GDPR (together, the UK GDPR and the EU GDPR, the GDPR). Under the UK GDPR, companies established in the UK and companies not established in the UK but who process personal information of individuals in the UK in relation to the offering of goods or services to those individuals, or to the monitoring of their behavior will be subject to the UK GDPR. As such, the GDPR applies to us to the extent we are established in an EU Member State or the UK, we are processing personal information in the context of an establishment in an EU Member State or the UK or we are processing personal information in relation to the offering of goods or services to individuals in the EEA or the UK or monitoring their behavior.

The GDPR imposes onerous and comprehensive privacy, data protection, and data security obligations onto controllers, including, as applicable: (i) contractual privacy, data protection, and data security commitments, including the requirement to implement appropriate technical and organizational measures to safeguard personal information processed; (ii) establishing means for individuals to exercise their data protection rights (e.g., the right to erasure of personal information); (iii) limitations on retention and the amount of personal information processed; (iv) additional requirements pertaining to sensitive information (such as health data); (v) data breach notification requirements to: (x) supervisory authorities without undue delay (and no later than 72 hours where feasible) after becoming aware of the breach, unless the breach is unlikely to result in a risk to the data subjects' rights and freedoms; and/or (y) concerned individuals where the breach is likely to result in a high risk to their rights and freedoms; (vi) requirements to process personal information lawfully including specific requirements for obtaining valid consent from data subjects where consent is the lawful basis for processing; (vii) obligations to consider data protection as any new products or services are developed and designed; and (viii) accountability and transparency requirements, which require controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects(such as clinical trial subjects and investigators) regarding processing. The GDPR also provides that EU Member States and the UK (as applicable) may introduce further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share personal information subject to the GDPR, cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition.

In addition, the EU GDPR also prohibits the transfer of personal information from the EEA to countries that the European Commission does not recognize as having an "adequate" level of data protection unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. Data protection laws in the UK (as discussed below) and Switzerland impose similar restrictions. One of the primary safeguards allowing U.S. companies to import personal information from the EU and Switzerland had historically been certification to the EU-U.S. Privacy Shield framework, which is administered by the U.S. Department of Commerce, and Swiss-U.S. Privacy Shield framework respectively. However, the EU-U.S. Privacy Shield framework was invalidated as a mechanism to legitimize international transfers in July 2020 in the "Schrems II" decision handed down by the Court of Justice of the EU and imposed further restrictions on the use of standard contractual clauses (SCCs). The Schrems II decision also led to a requirement for companies to carry out a transfer impact assessment (TIA) which, among other things, assess laws governing access to personal information in the recipient country and considers whether supplementary measures that provide privacy protections additional to those under the EU SCCs will need to be implemented to ensure an "essentially equivalent" level of data protection to that afforded in the EU. Similarly, the Swiss-U.S. Privacy Shield framework was declared as inadequate by the Swiss Federal Data Protection and Information Commissioner in light of the Schrems II decision.

On October 7, 2022, the U.S. President introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework (DPF), and on July 10, 2023, the EC adopted its Final Implementing Decision granting the U.S. adequacy (Adequacy Decision) for EU-U.S. transfers of personal information for companies that self-certify to the DPF. Entities relying on EU SCCs for transfer to the U.S. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U.S. national security safeguards and redress. However, any transfers by us or our vendors of personal information subject to the EU GDPR may not comply with European data protection law, may increase our exposure to the EU GDPR's heightened sanctions for violations of its cross-border data transfer restrictions, and may reduce demand from companies subject to European data protection laws.

Complying with the GDPR involves rigorous and time-intensive processes that may cause us to incur certain operational costs and/or require us to change our business practices. There may also be a risk that the measures will not be implemented correctly or that individuals within the business will not be fully compliant with the required procedures. If there are breaches of these measures, we could face significant administrative and monetary sanctions as well as reputational damage which may have a material adverse effect on our operations, financial condition and prospects. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves, may cause us to incur substantial operational costs or require us to change our business practices. There may also be a risk that the measures will not be implemented correctly or that individuals within the business will not be fully compliant with the required procedures. There is a risk that we could be impacted by a cybersecurity incident that results in loss or unauthorized disclosure of personal information, potentially resulting in us facing harms similar to those described above.

Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements, potential significant fines for non-compliance of up to the greater of €20 million (under the EU GDPR) or £17.5 million (under the UK GDPR) or 4% of consolidated annual global turnover and restrictions or prohibitions on data processing. The GDPR identifies a list of points to consider when determining the level of fines to impose (including the nature, gravity and duration of the infringement). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

The UK GDPR also imposes similar restrictions on transfers of personal information from the UK to jurisdictions that the UK Government does not consider "adequate", including the U.S. It should also be noted that the UK Government has published its own form of EU SCCs known as the UK International Data Transfer Agreement together with an International Data Transfer Addendum to the new EU SCCs. The UK Information Commissioner's Office (ICO) has also published its version of the TIA and guidance on international transfers, although entities may choose to adopt either the EU or UK style TIA. Further, on September 21, 2023, the UK Secretary of State of Science, Innovation and Technology established a UK-U.S. data bridge (i.e., a UK equivalent of the Adequacy Decision) and adopted UK regulations to implement the UK-U.S. data bridge ("UK Adequacy Regulations"). Personal information may now be transferred from the UK under the UK-U.S. data bridge through the UK extension to the DPF to organizations self-certified under the UK extension to DPF.

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

Regulation of privacy, data protection and data security has also become more stringent in the United States. HIPAA imposes requirements to protect the privacy and security of protected health information ("PHI") and to provide notification in the event of a breach of PHI. Violations of HIPAA are punishable by civil money penalties and, in some cases, criminal penalties and imprisonment. HHS' Office for Civil Rights ("OCR"), which is responsible for enforcing HIPAA, also may enter into resolution agreements requiring the payment of a civil money penalty and/or the establishment of a corrective action plan to address violations of HIPAA. Pursuant to HIPAA, HHS has adopted privacy regulations, known as the privacy rule, to govern the use and disclosure of PHI (the "Privacy Rule"). HHS has also adopted data security regulations (the "Security Rule") that require Covered Entities (including health care providers) and Business Associates to implement administrative, physical and technical safeguards to protect the integrity, confidentiality and availability of PHI that is electronically created, received, maintained or transmitted (such as between us and our affiliated practices).

Numerous state and certain other federal laws protect the confidentiality of health information and other personal information, including but not limited to state medical privacy laws, state laws protecting personal information, state data breach notification laws, state genetic privacy laws, human subjects research laws and federal and state consumer protection laws. For example, the CCPA, which took effect on January 1, 2020, give California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. The CCPA was substantially expanded on January 1, 2023, when the CPRA amendments to the CCPA became fully operative. The CPRA amendments, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CCPA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law. Regulation of privacy, data protection and data security has also become more stringent in the United States, with several new laws being enacted at the state level. For instance, additional states have enacted laws related to consumer privacy, such as Colorado, Connecticut, Utah, and Virginia. While these new laws generally include exemptions for HIPAA-covered data, they add layers of complexity to compliance in the U.S. market, and could increase our compliance costs and adversely affect our business. While these laws generally include exemptions for HIPAA-covered and clinical trial data, they impact the overall privacy landscape. Multiple other states and the federal government are considering enacting similar legislation, demonstrating a strong trend towards more stringent state privacy, data protection and data security legislation in the U.S., which could increase our potential liability and adversely affect our business. Other states have passed or amended existing state privacy laws to impose enhanced privacy and cybersecurity obligations for consumer health data, such as, the Washington My Health My Data Act and Nevada's Consumer Health Data Privacy Law. For instance, Washington State passed the "My Health My Data Act" with respect to "consumer health data" which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health" and which will go into effect in 2024 with additional privacy rights and compliance obligations.

Lawmakers and regulatory bodies at the federal level have been considering more detailed regulation regarding these subjects and the privacy and security of personal information. For example, the FTC recently published an advance notice of proposed rulemaking on "commercial surveillance" and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. The FTC's rulemaking may create change throughout the economy and broader data ecosystem. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information.

Additionally, the OCR has issued a Notice of Proposed Rulemaking, which propose a number of changes to the HIPAA Privacy Rule, with updates to the HIPAA Privacy Rule expected in 2024.

The Federal Trade Commission (FTC) has authority under Section 5 of the FTC Act to regulate unfair or deceptive practices, and has used this authority to initiate enforcement actions against companies that implement inadequate controls around privacy and information security in violation of their externally facing policies. The FTC has recently brought several cases alleging violations of Section 5 of the FTC Act with respect to health information, and has proposed rulemaking on privacy and data security.

Compliance with applicable U.S. and foreign privacy, data protection, and data security laws and regulations may result in government investigations or cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign privacy, data protection, and data security laws and regulations could result in government investigations or enforcement actions (which could include civil or criminal penalties), private litigation, claims, or public statements against us and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data protection, and data security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, reputation, financial performance and business, and operations. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations and policies that are applicable to the business of our customers may limit the adoption and use of, and reduce the overall demand for, our products and services.

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

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

We, our partners, our CROs, our CMOs, and other business vendors on which we rely depend on information technology and telecommunication systems for significant elements of our operations, including, for example, systems handling human resources, financial reporting and controls, regulatory compliance and other infrastructure operations. Notwithstanding the implementation of security measures, given the size and complexity of our information technology systems and those of our third party vendors and other contractors and consultants, and the increasing amounts of proprietary, confidential and sensitive information that they maintain, such information technology systems have been subject to and remain vulnerable to breakdown, service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure, or that of our third party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through accidental actions or omissions by trusted insiders, cyber attacks or cyber intrusions, including by computer hackers, viruses, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, the increased usage of computers operated on home networks due to the shelter-in-place or similar restrictions related to the COVID-19 pandemic may make our systems more susceptible to security breaches. For example, in March 2021, MSK provided notice that MSK was one of many customers impacted by a data breach at Accellion, Inc., which provides a document-sharing system. MSK subsequently notified us that certain documents related to one of our discontinued programs were subject to the breach, which compromise we deemed immaterial. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, we and our third party service providers frequently defend against and respond to cyber attacks, and our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third party service providers could cause significant interruptions to our operations, including preventing us from conducting tests or research and development activities and preventing us from managing the administrative aspects of our business. For example, the loss of clinical study data from completed, ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, sophisticated operating system software and applications that we procure from third parties may contain defects in design or manufacture, including vulnerabilities, "bugs" and other problems that could unexpectedly interfere with the operation of our networks, system, or our processing of personal information or other data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

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

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

We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third party vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our services and technologies could be delayed. Furthermore, significant disruptions of our internal information technology systems or those of our third party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. For example, in November 2023, we experienced a cybersecurity incident which resulted in unauthorized access of certain systems within our IT environment and a third party obtaining certain of our documents. Such unauthorized access was detected and contained within several hours and it was determined the third party did not access any of our material confidential information. Following such incident, we've taken additional measures to strengthen our IT environment.

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

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

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

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

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

We are subject to income and non-income based taxes in the U.S. and various jurisdictions outside the U.S. Our business and financial condition could be adversely affected by changes in federal, state, local or international tax laws, changes in taxing jurisdictions' administrative interpretations, decisions, policies and positions, changes in accounting principles, applicability of withholding taxes, and changes to our business operations. For example, U.S. legislation such as the Tax Act, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), and the American Rescue Act, made significant changes to the corporate tax rate, the potential realization of net deferred tax assets relating to our operations, taxation of foreign earnings, and deductibility of expenses, and could have a material impact on our financial position or results of operations.

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

Our ability to use our federal and state net operating losses (NOLs) and certain other tax attributes 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 or other tax attributes.

As of December 31, 2023, we had significant U.S. federal and state NOLs due to prior period losses. Under the Tax Cuts and Jobs Act (the Tax Act), federal NOLs generated in tax years beginning on or after January 1, 2018 may be carried forward indefinitely, but the utilization of such federal NOLs is limited to 80% of current year taxable income. States vary in conformity to all or portions of the Tax Act. The Tax Act did not have a material impact to our financial statements.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an "ownership change". Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year testing period. Similar rules may apply under state tax laws. We performed a Section 382 analysis of transactions in our stock through December 31, 2023 and concluded that we have experienced ownership changes since inception that we believe under Section 382 of the Code will result in limitations on our ability to use certain pre-change NOLs and credits. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and, in the case of NOLs generated before January 1, 2018 may expire unused. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations. Similar provisions of state tax

law may also apply to limit the use of accumulated state tax attributes. Regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, may cause our existing tax attributes to expire, decrease in value or otherwise be unavailable to offset future income tax liabilities.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established policies and processes designed to assess, identify, and manage material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes.

We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We monitor our environments to identify cybersecurity threats, as well as assess our environments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following our monitoring, we adjust, implement and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with our Chief Information Officer, who reports to our Chief Financial Officer, to manage any identified risks and mitigation process. As part of our overall cyber security framework, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with our information technology (IT) department and management. Personnel at all levels and departments are made aware of our cybersecurity policies through ongoing training.

We engage third-party vendors in connection with our cybersecurity risk monitoring and processes. These service providers assist in our design and implementation of our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We also maintain insurance coverage that is intended to address certain aspects of cybersecurity risks.

Notwithstanding any of these measures, our systems and networks remain potentially vulnerable to known or unknown cybersecurity attacks and other threats, any of which could have a material adverse effect on our consolidated results of operations, financial condition and cash flows. We have experienced, and will continue to experience, cyber incidents in the normal course of our business. As of the date of this report, we have not identified any risks from cybersecurity threats, including those from any previous cybersecurity incidents, that have materially affected us, our business strategy, results of operation or financial condition. However, there can be no assurances that a cybersecurity threat or incident that could have a material impact on us will not occur in the future. For additional information on the risks we face from cybersecurity threats, please see the risk factor titled, "If our security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our services, compromise sensitive information related to our business, harm our reputation, trigger our breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business." in Item 1A. "Risk Factors."

Governance

The Audit Committee of the Board of Directors is responsible for the primary oversight of our information security programs, including relating to cybersecurity. The Audit Committee receives status updates on at least a semi-annual basis from our Chief Information Officer on, among other things, our cyber risks and threats, the status of projects to strengthen our information security systems, assessments of our security program, and our views of the emerging threat landscape. The Chair of the Audit Committee regularly reports to the Board on cybersecurity risks and other matters reviewed by the Audit Committee. In addition, all Board members have access to the materials for each Audit Committee meeting.

Our Chief Information Officer is responsible for the oversight of our cybersecurity risks. We have implemented a security incident response plan and use this incident response framework as part of the process we employ to keep the Audit Committee and our executive management informed about cybersecurity risks and to monitor the prevention, detection, mitigation and remediation of

cybersecurity incidents. The plan is a set of procedures and tasks that our incident response team, under the direction of the Chief Information Officer, executes with the goal of ensuring timely identification and appropriate resolution of cybersecurity incidents. In addition, we validate compliance with our internal data security controls through the use of security monitoring tools.

Our Chief Information Officer has over 25 years of IT experience and has a thorough understanding of enterprise level cyber security framework. Our Chief Information Officer has also participated in cybersecurity reviews and implementations including various tools and platforms for over 10 years and drives strategic cyber security implementations based on industry best practices that helps us strengthen our security posture on a continuous basis.

Item 2. Properties

Our corporate headquarters are located in Thousand Oaks, California and consists of approximately 51,160 square feet of office space under a lease agreement that expires in February 2026.

In March 2021, we entered into a new lease agreement for approximately 33,659 square feet of office, lab and warehouse space in Thousand Oaks, California. The initial 10.5-year term of this lease commenced in August 2021. We have the option to extend this lease for two additional five-year periods after the initial term.

In November 2023, we entered into an amended lease agreement for our office and lab space in Aurora, Colorado, to extend the term of our lease agreement through April 2025.

In April 2022, we assigned our lease of approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California, which expires in April 2033, to FDB as part of the Fujifilm Transaction. We remain joint and severally liable for obligations related to the assigned lease.

We lease office space in South San Francisco, California, under a non-cancellable lease agreement through May 2025. In October 2022, we entered into a sub-lease agreement with a third party for this office space. The sub-lease term commenced in November 2022 and expires in May 2025, with no option to extend the sub-lease term.

We use our leased spaces in Thousand Oaks, California and Aurora, Colorado for our translational and preclinical sciences, analytical development and process science functions. These facilities support our product pipeline and process development and leverage our allogeneic cell therapy platform to drive innovation. We believe our existing facilities are in good operating condition and suitable for the conduct of our business.

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 March 20, 2024, there were 4 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 all of our future earnings, if any, to finance the growth and development 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.

Item 6. [Reserved]

Not Applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our 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 leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune disease. Tab-cel (tabelecleucel), our lead program in Phase 3 clinical development in the U.S., has received marketing authorization approval (MAA) under the proprietary name Ebvallo™ for commercial sale in the European Union (EU) by the European Commission (EC) and for commercial sale and use in the United Kingdom (UK) by the Medicines and Healthcare products Regulatory Agency (MHRA). We are the most advanced allogeneic T-cell immunotherapy company and intend to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-driven diseases or other serious diseases through incorporation of engineered chimeric antigen receptors (CARs) or T-cell receptors (TCRs). We are applying this one platform, that does not require TCR or human leukocyte antigen (HLA) gene editing, to create a robust pipeline. Our strategic priorities are:

- ***Tab-cel®***: Our most advanced T-cell immunotherapy program, tab-cel, has received MAA for commercial sale in the EU and the UK under the proprietary name Ebvallo and is partnered with Pierre Fabre Medicament (Pierre Fabre) for commercialization in Europe and potential commercialization, if approved, worldwide, including in the U.S. Tab-cel is currently in Phase 3 development in the U.S. for patients with EBV- associated post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-driven diseases; and

- ***ATA3219***: Allogeneic CAR T targeting CD19, currently in Phase 1 development is being developed as a potential best-in-class product intended to target B-cell malignancies and autoimmune diseases, based on a next generation 1XX co-stimulatory domain and the innate advantages of EBV T cells as the foundation for an allogeneic CAR T platform.

In addition to the aforementioned strategic priorities, we also have a number of preclinical programs, including ATA3431, an allogeneic dual CAR T immunotherapy targeting both CD19 and CD20 for B-cell malignancies; and a potential next generation EBV vaccine which is differentiated from earlier EBV vaccine efforts that solely focused on B cell responses to EBV. We have paused development on ATA188, an allogeneic T-cell immunotherapy targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS), while we explore strategic options for this asset.

Our T-cell immunotherapy platform is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. We select the appropriate set of cells for use based on a patient's unique immune profile. We estimate that only four and six unique ATA3219 lots will be needed to cover approximately 90% of U.S. NHL and lupus patients, respectively. One of our contract manufacturing organizations (CMOs) has completed commercial production qualification activities for tab-cel and another of our CMOs is currently in the process of completing commercial production qualification activities for tab-cel while we manufacture inventory according to Pierre Fabre's commercial product supply strategy.

In October 2021, we entered into the Commercialization Agreement with Pierre Fabre (Pierre Fabre Commercialization Agreement), pursuant to which we granted to Pierre Fabre an exclusive, field-limited license to commercialize and distribute Ebvallo in Europe and select emerging markets in the Middle East, Africa, Eastern Europe and Central Asia (the Initial Territory) following regulatory approval. As contemplated by the Pierre Fabre Commercialization Agreement, we entered into (i) a Manufacturing and Supply Agreement (ii) a Pharmacovigilance Agreement (iii) and a Quality Agreement, in each case, with Pierre Fabre to further advance our partnership with Pierre Fabre. In September 2022, we amended the Pierre Fabre Commercialization Agreement and received an additional $30 million milestone payment from Pierre Fabre following EC approval of Ebvallo for EBV+ PTLD and subsequent filing of the MAA transfer to Pierre Fabre, in exchange for, among other things, a reduction in: (i) royalties we are eligible to receive as a percentage of net sales of Ebvallo in the Initial Territory, and (ii) the supply price mark up on Ebvallo purchased by Pierre Fabre. Additionally, we agreed to extend the time period for provision of certain services to Pierre Fabre under the Pierre Fabre Commercialization Agreement. In December 2022, we entered into a Purchase and Sale Agreement (HCRx Agreement) with HCR

Molag Fund L.P. (HCRx,) a Delaware limited partnership. Pursuant to the terms of the HCRx Agreement, we received a total investment amount of $31.0 million in exchange for HCRx being entitled to receive a portion of the tiered, sales-based royalties for Ebvallo, in amounts ranging from the mid-single digits to significant double digits, as well as certain milestone payments, both related to the Initial Territory and otherwise payable to us by Pierre Fabre. The total royalties and milestones payable to HCRx related to the Initial Territory under the HCRx Agreement are capped between 185% and 250% of the total investment amount by HCRx, dependent upon the timing of such royalty and milestone payments to HCRx.

On October 31, 2023, we entered into an amended and restated Pierre Fabre Commercialization Agreement (A&R Commercialization Agreement), pursuant to which we expanded Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute tab-cel (Ebvallo) to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of $20.0 million for the expanded exclusive license grant, for which the cash was received in January 2024. We will also be entitled to receive an aggregate of up to $620.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory including up to $100.0 million in potential regulatory milestones through approval by the United States Food and Drug Administration (FDA) of a biologics license application (BLA) for tab-cel. Of the $100.0 million in potential regulatory milestones, we expect to receive $20.0 million in April 2024 based on the positive pre-BLA meeting, an additional $20.0 million in connection with BLA acceptance, and up to $60.0 million in potential regulatory milestones in connection with BLA approval. We are eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel in each such country. Royalty payments may be reduced in certain specified customary circumstances. Royalties and milestones from the commercialization of Ebvallo in the Initial Territory remain subject to the HCRx Agreement.

During the applicable period specified in the A&R Commercialization Agreement, we will be responsible, at Pierre Fabre's cost, to continue conducting the ongoing Phase 3 ALLELE clinical study and the Phase 2 multi-cohort clinical study. We will also be responsible, at Pierre Fabre's cost, for certain other activities directed to obtaining regulatory approval in the United States for tab-cel for EBV-associated post-transplant lymphoproliferative disease pursuant to the terms of the A&R Commercialization Agreement. Pierre Fabre will be responsible, at its cost, for obtaining and maintaining all other required regulatory approvals and for commercialization and distribution of tab-cel in the Territory, including conducting any other clinical study required.

Prior to the transfer of manufacturing responsibility to Pierre Fabre, we will be responsible for manufacturing and supplying tab-cel to Pierre Fabre for commercialization in the Territory at cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab-cel in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of i) the date on which all activities relating to the transfer of tab-cel manufacturing, pursuant to the A&R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, throughout the remainder of the term of the A&R Commercialization Agreement. Pierre and we are to use commercially reasonable efforts to achieve this prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the first BLA.

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

Our research facilities in Thousand Oaks, California (ARC) and Aurora, Colorado contain our translational and preclinical sciences, analytical development and process science functions. These facilities support our product pipeline, process development and leverage our allogeneic cell therapy platform to drive innovation.

In January 2022, we entered into an asset purchase agreement with FUJIFILM Diosynth Biotechnologies California, Inc. (FDB) and, for certain limited purposes, FUJIFILM Holdings America Corporation, to sell all of the Company's right, title and interest in and to certain assets related to the Atara T-Cell Operations and Manufacturing facility (ATOM Facility) located in Thousand Oaks, California for $100 million in cash, subject to potential post-closing adjustments pursuant to the asset purchase agreement (the Fujifilm Transaction). The closing of the Fujifilm Transaction occurred on April 4, 2022. We also entered into a Master Services and Supply Agreement with FDB (Fujifilm MSA) that became effective upon the closing and could extend for up to ten years. Pursuant to the Fujifilm MSA, FDB will supply us with specified quantities of our cell therapy products (if approved) and product candidates, manufactured in accordance with cGMP standards. The Fujifilm MSA does not obligate us to purchase products and product candidates exclusively from FDB.

We also work with Charles River Laboratories (CRL) pursuant to a Commercial Manufacturing Services Agreement (CRL MSA) that we entered into in December 2019. Pursuant to the CRL MSA, CRL provides manufacturing services for our product and certain intermediates. We further amended the CRL MSA to extend the term until the earlier of March 31, 2024 or upon receipt of certain batches of our product and product candidates. We are currently in negotiations with CRL for a new commercial drug product supply agreement to be effective upon the expiration of the CRL MSA. However, there can be no assurance that we will be able to enter into a new commercial drug product supply agreement with CRL on terms favorable or acceptable to us, or at all. If we are unable to enter into a new commercial drug product supply agreement or extend the CRL MSA, we may need to identify alternative sources of drug product supply.

We have non-cancellable minimum commitments for products and services, subject to agreements with a term of greater than one year, with clinical research organizations and CMOs.

In November 2023, we announced a reduction in force of approximately 30% of our workforce at that time. This workforce reduction resulted in total restructuring charges of $6.7 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California Worker Adjustment and Retraining Notification (WARN) Act. In most cases, the severance payments were paid as a lump sum in January 2024. All of the severance costs represent cash expenditures.

In January 2024, we announced another reduction in force of approximately 25% of total workforce. We expect to recognize approximately $4.5 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2024. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from February 2024 through January 2025. The majority of the associated costs represent cash expenditures.

Financial Overview

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

Our net losses were $276.1 million and $228.3 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $2.0 billion. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. As of December 31, 2023, our cash, cash equivalents and short-term investments totaled $51.7 million, which we intend to use to fund our operations.

Revenues

We have only just begun to generate commercialization revenues under the A&R Commercialization Agreement, following the December 2022 EC approval of Ebvallo. Our commercialization revenue recognized to date is derived from agreements with Pierre Fabre, primarily related to upfront license fees, milestone payments and amounts recognized from the sale of zero-cost inventories for which all performance obligations are complete, and is subject to the terms of the HCRx Agreement. We do not retain any meaningful milestone or royalty payments related to the Initial Territory under the A&R Commercialization Agreement until the applicable royalty cap under the HCRx Agreement is met, if at all, or until regulatory approval is achieved in the US or for another market within the Additional Territory. Our license and collaboration revenue recognized to date is primarily derived from agreements with Bayer AG, which terminated as of July 31, 2022.

We expect that any revenue we generate from the A&R Commercialization Agreement, subject to the terms of the HCRx Agreement, will fluctuate from period to period as a result of the timing and number of inventory purchases by Pierre Fabre, potential milestone achievement, any potential regulatory approvals and the timing of manufacturing and cell selection technology transfer to Pierre Fabre.

Cost of commercialization revenue

Cost of commercialization revenue consists primarily of expenses associated with cell selection services performed for Pierre Fabre, in-license sales-related milestone costs, period manufacturing expenses and the lower of cost or net realizable value adjustments to inventories. All Ebvallo sold to Pierre Fabre to date had been produced prior to receiving regulatory approval of Ebvallo. Costs incurred to produce Ebvallo prior to regulatory approval, referred to as zero cost inventories, have been recorded as

research and development expense in our consolidated statement of operations and comprehensive income (loss). Once we begin selling Ebvallo produced after receiving regulatory approval and in a qualified manufacturing facility, and as revenue is recognized on such Ebvallo shipments, cost of commercialization revenue will also include direct and indirect costs related to the production of Ebvallo. Such costs include, but are not limited to, CMO costs, quality testing and validation, materials used in production, and an allocation of compensation, benefits and overhead costs associated with employees involved with production.

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

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

•continuing to enroll patients in our Phase 3 clinical study of tab-cel for the treatment of patients with EBV+ PTLD after HCT and SOT who have failed rituximab;

•process development, testing and manufacturing of drug supply to support clinical and IND-enabling studies;

•continuing to develop product candidates based on our next-generation CAR T programs;

•continuing to develop our product candidates in additional indications, including tab-cel for EBV+ cancers;

•continuing to develop other preclinical product candidates; and

•leveraging our relationships and experience to in-license or acquire additional product candidates or technologies.

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

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

•the availability of qualified drug supply for use in our ongoing Phase 3 or other clinical studies;

•the scope, rate of progress, and expenses of our ongoing clinical studies, potential additional clinical studies and other research and development activities;

•the potential review or reanalysis of our clinical study results;

•future clinical study results;

•uncertainties in clinical study enrollment rates or discontinuation rates of patients;

•potential additional safety monitoring or other studies requested by regulatory agencies;

•changing medical practice patterns related to the indications we are investigating;

•significant and changing government regulation;

•disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic; and

•the timing and receipt of any regulatory approvals, as well as potential post-market requirements.

The process of conducting the necessary clinical research to obtain approval from the FDA and other regulators is costly and time consuming and the successful development of our product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this report titled "1A. Risk Factors." As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval.

General and Administrative Expenses

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

Gain on sale of ATOM Facility

The gain on sale of the ATOM Facility consists of the consideration received from FDB, less transaction costs and the carrying value of assets sold.

Interest Income

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

Interest Expense

Interest expense consists primarily of interest expense recorded in connection with the HCRx Agreement.

Provision for Income Taxes

Provision for income taxes consists primarily of income taxes in U.S. states and foreign jurisdictions. Our effective tax rate was 0% for the years ended December 31, 2023 and 2022.

Critical Accounting Policies and Significant 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.

Revenue Recognition

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

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

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price (SSP) of each distinct performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and other promises cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using an appropriate recognition method based on the nature of the performance obligations. We utilize judgment to assess the pattern of delivery of the performance obligation. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. A significant change in the assumptions and estimates, such as forecasted costs or the extent and timing of patient demand, and expected dates of technology transfer, could have a material impact on the timing and amount of revenue recognized in future periods or adjustments to cumulative revenue recognized in the period of change.

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

Certain judgments affect the application of our revenue recognition policy. For example, we record short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months, and long-term deferred revenue consists of amounts that we expect will be recognized after the next 12 months. This estimate is based on forecasted patient demand, our current operating plan, and expected dates of technology transfer, and if these items should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate and accrue expenses, the largest of which is related to research and development expenses, including those related to clinical studies and clinical product candidate 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 which we have not yet been invoiced or otherwise notified of the actual costs incurred.

Costs for preclinical studies, clinical studies and product candidate 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 goods and services delivered. 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 asset and recognized as expense as the services are provided.

For the years ended December 31, 2023 and 2022, there were no material changes from our estimates of accrued research and development expenses. We do not believe there is a reasonable likelihood that there will be a material change in the future estimates of accrued research and development expenses. However, if actual results are not consistent with our estimates, we may be exposed to changes in accrued research and development expenses that could be material or the accrued research and development expenses reported in our financial statements may not be representative of the actual economic cost of accrued research and development.

Stock-based Compensation

We have stock-based compensation programs, which include an employee incentive plan, an inducement plan and an employee stock purchase plan. See Note 2 – "Summary of Significant Accounting Policies" and Note 11 – "Stockholders' Equity" in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for a complete discussion of our stock-based compensation programs. We account for stock-based compensation expense, including the expense for grants of restricted stock units (RSUs) and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant. The fair value of our RSUs is measured at the market price of our common stock on the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model.

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

•Expected term – We derived the expected term for employee stock awards using the "simplified" method (the expected term is determined as the average of the time-to-vesting and the contractual life of the options), as we have limited historical information to develop expectations about future exercise patterns and post vesting employment termination behavior. Expected term for non-employee awards is based on the remaining contractual term of an option on each measurement date.

•Expected volatility – In 2021 and 2022, volatility was estimated using an average of our historical volatility and comparable public companies' volatility for similar terms. Beginning in 2023, volatility is based solely on our stock price historical volatility.

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

•Risk-free interest rate – The risk-free interest rate is based on the yields of U.S. Treasury securities with expected terms similar to that of the associated award.

•The fair value of our common stock is measured at the market price on the measurement date.

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

Accounting for Income Taxes

See Note 12 – "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 our income tax expense, as well as the temporary differences that exist as of December 31, 2023.

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. We are also required to exercise judgment with respect to the realization of our net deferred tax assets. We evaluate all positive and negative evidence and exercise judgment regarding past and future events to determine if it is more likely than not that all or some portion of the deferred tax assets may not be realized. If appropriate, a valuation allowance is recorded against deferred tax assets to offset future tax benefits that may not be realized.

We do not believe that there is a reasonable likelihood that there will be a material change in our liability for uncertain income tax positions or our effective income tax rate. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to losses that could be material. We recorded a valuation allowance of approximately $475.0 million as of December 31, 2023 related primarily to net operating loss carryforwards, capitalized research expenses, tax credit carryforwards and stock-based compensation.

Liability related to the sale of future revenues

To the extent we account for the sale of future revenues as debt in accordance with ASC 470, we amortize the liability and recognize interest expense related to the sale of future revenues using the effective interest rate method over the estimated life of the underlying agreement. The liability and related interest expense are based on our current estimate of expected future payments over the life of the arrangement. We re-assess the amount and timing of expected payments each reporting period using a combination of internal projections and forecasts from external resources and record interest expense on the carrying value of the liability using the imputed effective interest rate. To the extent our estimates of future payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, this could impact the amount of interest expense we record each period as well as the amount and classification of the liability. We will account for any such changes by adjusting the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the liability and amortization period requires that we make estimates that could impact the effective interest rate, short-term and long-term classification of the liability and the period over which the liability will be amortized.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

Revenues

Revenue consisted of the following in the periods presented:

	Year ended December 31,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Commercialization revenue	$ 7,886	$ —	$ 7,886
License and collaboration revenues	687	63,573	(62,886)
Total revenue	$ 8,573	$ 63,573	$ (55,000)

Commercialization revenues were $7.9 million in 2023 as compared to none in 2022. The increase in 2023 was due to the EC marketing authorization for commercial sale and use of Ebvallo in the EU was transferred to Pierre Fabre in February 2023 and no commercialization revenue could be recognized prior to this occurring.

License and collaboration revenues were $0.7 million in 2023 as compared to $63.6 million in 2022. The decrease in 2023 was primarily due to Bayer having notified us in May 2022 of its decision to terminate the Bayer Agreements, which resulted in the recognition of the remaining deferred revenue related to the Bayer Agreements in the second quarter of 2022. The only license and collaboration revenue recognized subsequent to the termination of the agreements with Bayer in the third quarter of 2022 has been related to certain early access program cost reimbursements per the A&R Commercialization Agreement.

Cost of commercialization revenue

Cost of commercialization revenue consisted of the following in the periods presented:

	Year ended December 31,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Cost of commercialization revenue	$ 8,886	$ —	$ 8,886

Costs of commercialization revenues were $8.9 million in 2023 compared to none in 2022. The increase primarily related to adjustments to reflect current period work-in-process inventory at net realizable value, idle capacity period manufacturing costs and in-license sales-related milestone expense. Prior to receiving EC regulatory approval for Ebvallo in the EU in December 2022, we recorded all costs incurred in the manufacture of Ebvallo to be sold upon commercialization as research and development expense. As a result, Ebvallo inventories manufactured before EC regulatory approval, referred to as zero cost inventories, were expensed as research and development and are therefore excluded from the cost of commercialization revenue. Ebvallo manufacturing costs incurred after EC regulatory approval are capitalized into inventory. All commercialization revenue recognized to date relates to zero cost inventories and all Ebvallo sold to Pierre Fabre in the year ended December 31, 2023 were zero cost inventories.

Research and development expenses

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

	Year ended December 31,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Program-specific expenses			
Tab-cel® expenses	$ 22,088	$ 40,597	$ (18,509)
ATA188 expenses	21,308	26,776	(5,468)
CAR T and other program expenses	9,523	10,728	(1,205)
Non program-specific expenses			
Employee and overhead expenses	159,437	186,339	(26,902)
Other non program-specific expenses	12,429	8,093	4,336
Total research and development expenses	$ 224,785	$ 272,533	$ (47,748)

Tab-cel expenses were $22.1 million in 2023 as compared to $40.6 million in 2022. The decrease in 2023 was primarily due to the capitalization of tab-cel manufacturing costs to inventory following EC regulatory approval in December 2022 and a decrease in European tab-cel regulatory filing and approval activities.

ATA188 expenses were $21.3 million in 2023 as compared to $26.8 million in 2022. The decrease in 2023 is primarily due to lower product development and manufacturing activities as a result of us pausing such activities while we awaited the results of the Phase 2 EMBOLD clinical trial primary analysis data. Following the announcement in November 2023 that the study did not meet its primary endpoint and the subsequent pause in the development of ATA188, we expect ATA188 expenses to be lower in future periods.

CAR T and other program expenses were $9.5 million in 2023 as compared to $10.7 million in 2022. The decrease in 2023 was primarily driven by higher manufacturing, development and outside services spend in 2022 leading up to the submission of the ATA3219 IND in mid-2023, partially offset by costs related to ATA3219 clinical trial start-up activities in the second half of 2023.

Non program specific expenses were $171.9 million in 2023 as compared to $194.4 million in 2022. The decrease in 2023 was primarily due to lower payroll and related costs, driven by the sale of the ATOM facility and August 2022 reduction in force, partially offset by increased costs associated with cross-program materials and outside services. In 2023 as compared to 2022, payroll and related costs decreased by $26.1 million; outside service costs decreased by $2.3 million; facility-related costs increased by $1.6 million; and other non-program specific costs increased by $4.3 million.

General and administrative expenses

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

	Year ended December 31,		
	2023	2022	(Decrease) Increase
	(in thousands)		
General and administrative expenses	$ 50,908	$ 71,553	$ (20,645)

General and administrative expenses were $50.9 million in 2023 as compared to $71.6 million in 2022. The decrease in 2023 was primarily driven by lower payroll and related costs as a result of the August 2022 reduction in force and lower outside service costs related to a reduction in US tab-cel commercial activities.

Other income (expense), net

	Year ended December 31,		
	2023	2022	Increase (Decrease)
	(in thousands)		
Interest income	$ 5,426	$ 3,059	$ 2,367
Interest expense	(5,285)	(373)	(4,912)
Other income (expense), net	(246)	(700)	454
Gain on sale of ATOM Facility	—	50,237	(50,237)
Total other income (expense), net	$ (105)	$ 52,223	$ (52,328)

Interest income was $5.4 million in 2023, as compared to $3.1 million in 2022. The increase in 2023 was primarily driven by higher investment yields, partially offset by lower balances of cash, cash equivalents and available-for-sale securities.

Interest expense was $5.3 million in 2023 as compared to $0.4 million in 2022. The higher interest expense in 2023 was due to interest expense recognized on the liability related to the sale of future revenues following us entering into the HCRx Agreement in December 2022.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012, we have funded our operations primarily through the issuance of common and preferred stock, issuance of pre-funded warrants to purchase common stock, upfront fees and milestone payments from the Bayer License Agreement and the A&R Commercialization Agreement and the sale of our ATOM Facility.

In the past three years, we have entered into two separate sales agreements with Cowen and Company, LLC (Cowen): in November 2021 (2021 ATM Facility) and in November 2023 (2023 ATM Facility). Each ATM facility provides or provided for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million, through Cowen, as our sales agent. We filed a registration statement on Form S-3 registering the offer and sale of these shares under the Securities Act (the 2023 Registration Statement). Upon the effectiveness of the 2023 Registration Statement, the 2021 ATM Facility was terminated, and no further sales can be made under the 2021 ATM Facility. The issuance and sale of these shares by us pursuant to the ATM facilities are deemed "at the market" offerings defined in Rule 415 under the Securities Act of 1933, as amended (Securities Act), and were registered under the Securities Act. Commissions of up to 3.0% are due on the gross sales proceeds of the common stock sold under each ATM facility.

During the year ended December 31, 2023, we sold an aggregate of 3,038,432 shares of common stock under our ATM facilities, at an average price of $0.83 per share, for gross proceeds of $2.5 million and net proceeds of $2.2 million, after deducting commissions and other offering expenses payable by us. Approximately $0.1 million of the $2.2 million net proceeds were received on January 2, 2024.

As of December 31, 2023, we had $98.2 million of common stock remaining and available to be sold under the 2023 ATM Facility.

From January 1, 2024 through March 15, 2024, we sold an additional 12,321,365 shares of common stock under the 2023 ATM Facility, at an average price of $0.77 per share, for gross proceeds of $9.5 million and net proceeds of $9.3 million, after deducting commissions and other offering expenses payable by us. As of March 15, 2024, we had $88.7 million of common stock remaining and available to be sold under the 2023 ATM Facility, subject to certain conditions as specified in the agreement.

We have incurred losses and negative cash flows from operations in each year since inception and have only just begun to generate commercialization revenues from the A&R Commercialization Agreement, following the December 2022 EU regulatory approval of Ebvallo, which is subject to the terms of the HCRx Agreement. We do not maintain any meaningful milestone or royalty payments from Pierre Fabre relative to the Initial Territory until the applicable royalty cap under the HCRx Agreement is met, if at all. We continue to incur significant research and development and other expenses related to our ongoing operations and expect to incur losses for the foreseeable future. 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 and other collaborations, strategic alliances and partnering arrangements. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings including by utilizing the 2023 ATM Facility, through potential collaboration, partnering or other strategic arrangements, or a combination of the foregoing. 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 or grant licenses or other rights on terms that are not favorable to us.

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, and corporate debt obligations.

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 25,841	$ 92,942
Short-term investments	25,884	149,877
Total cash, cash equivalents and short-term investments	$ 51,725	$ 242,819

Contractual Obligations and Commitments

We lease our corporate headquarters in Thousand Oaks, California, under a non-cancellable lease agreement for approximately 51,160 square feet of office space. 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.

We lease office space in South San Francisco, California under a non-cancellable lease agreement. In December 2021, we entered into a second amendment to extend the lease term through May 2025. The amended lease agreement does not include an option to extend the lease term. In October 2022, we entered into a sub-lease agreement with a third party for this office space. The sub-lease term commenced in November 2022 and expires in May 2025, with no option to extend the sub-lease term. Subsequently, we have moved our corporate headquarters to our office space in Thousand Oaks, California.

In May 2019, we entered into a lease agreement for approximately 8,800 square feet of office and lab space in Aurora, Colorado. In February 2021, we further amended this lease to add an additional 2,861 square feet of lab space. In November 2023, we entered into an amended lease agreement for our office and lab space in Aurora, Colorado, to extend the term of our lease agreement through April 2025. The contractual obligations during the lease term are not material.

In March 2021, we entered into a lease agreement for approximately 33,659 square feet of office, lab and warehouse space in Thousand Oaks, California. The initial 10.5-year term of this lease commenced in August 2021 and the contractual obligations during the initial term are $21.0 million in aggregate. We have the option to extend this lease for two additional five-year periods after the initial term.

In February 2017, we entered into a lease agreement (ATOM Lease) for approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California. The initial 15-year term of this lease commenced in February 2018, and the contractual obligations during the initial term are $16.4 million in aggregate. We have the option to extend this lease for two additional periods of ten and nine years, respectively, after the initial term. In April 2022, we assigned the ATOM Lease to FDB in connection with the closing of the sale of the ATOM Facility to FDB. We remain joint and severally liable for obligations related to the ATOM Lease. See Note 8 – “Leases” in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for further information on our lease obligations.

We enter into contracts in the normal course of business with clinical research organizations for clinical studies, with CMOs for clinical and commercial materials, and with other vendors for preclinical studies and supplies and other services and products for operating purposes. These contracts generally provide for termination for convenience following a notice period. We have non-cancellable minimum commitments for products and services, subject to agreements with a term of greater than one year with clinical research organizations and CMOs. See Note 10 – “Commitments and Contingencies” in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for further information on our contractual obligations and commitments.

Cash Flows

Comparison of the Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (192,977)	$ (270,430)
Investing activities	123,866	202,956
Financing activities	2,010	53,084
Net decrease in cash, cash equivalents and restricted cash	$ (67,101)	$ (14,390)

Operating activities

Net cash used in operating activities was $193.0 million in 2023 as compared to $270.4 million in 2022. The decrease of $77.4 million was primarily due to the $40.0 million received from Pierre Fabre in 2023 for development milestones met in December 2022, with no similar cash flows received in 2022.The remaining decrease was due to lower cash operating expenses in 2023 as compared to 2022, primarily due to lower compensation-related costs resulting from lower headcount driven by the sale of the ATOM facility in April 2022 and the August 2022 reduction in force, partially offset by an increase in net working capital from the capitalization of costs into inventory following the December 2022 EC regulatory approval of Ebvallo.

Investing activities

Net cash provided by investing activities in 2023 consisted of $208.7 million received from maturities and sales of available-for-sale securities, partially offset by $83.6 million used to purchase available-for-sale securities and $1.2 million in purchases of property and equipment.

Net cash provided by investing activities in 2022 consisted primarily of $293.0 million received from maturities and sales of available-for-sale securities, partially offset by $180.6 million used to purchase available-for-sale securities and $4.2 million in purchases of property and equipment.

Financing activities

Net cash provided by financing activities in 2023 consisted primarily of $2.1 million of net proceeds from ATM facilities and $0.9 million of net proceeds from employee stock award transactions.

Net cash provided by financing activities in 2022 consisted primarily of $21.9 million of net proceeds from ATM facilities, $30.6 million of net proceeds from the sale of future royalties and $1.9 million of net proceeds from employee stock award transactions.

Operating Capital Requirements and Plan of Operations

We expect that existing cash, cash equivalents and short-term investments, combined with certain anticipated payments from the A&R Commercialization Agreement, as well as cost reductions from completed workforce reductions and operating efficiencies resulting from our planned transition of substantially all activities relating to tab-cel at the time of the BLA transfer to Pierre Fabre, will enable us to fund our planned operations into 2027. Such anticipated payments are estimates based on assumptions and plans that are subject to change and such changes could materially impact our expected cash runway. These assumptions include the receipt of future payments that are dependent upon the successful filing and approval of the tab-cel BLA, as well as the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time. We do not know when, or if, we will generate sufficient revenue from commercialization to offset our operating expenses. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the accumulated losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need to raise substantial additional funding to finance our planned operations in the long-term.

Our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. We do not have any committed external source of funds other than milestone and royalty payments that we may receive under the A&R Commercialization Agreement, subject to the terms of the HCRx Agreement. We do not retain any meaningful milestone or royalty payments related to the Initial Territory from Pierre Fabre until the applicable royalty cap under the HCRx Agreement is met, if at all.

Our existing cash, cash equivalents and short-term investments as of December 31, 2023 will not be sufficient to fund our planned operations for at least the next 12 months after the date of issuance of these financial statements. These conditions raise substantial doubt about our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements.

In order to complete the process of obtaining regulatory approval for any of our product candidates that have not received approval, we will require substantial additional funding. We expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings, through potential collaboration, partnering or other strategic arrangements, or a combination of the foregoing. If we are unable to obtain sufficient funding on acceptable terms, we could be forced to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates.

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

•the timing, costs and results of our ongoing and planned clinical and preclinical studies for our product candidates;

•our success in establishing and maintaining manufacturing relationships with CMOs;

•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 by our partners and the amount of revenues received from commercial sales of our product candidates;

•the timing of proceeds from, and our ability to perform under, the A&R Commercialization Agreement, subject to the HCRx Agreement, as well as the terms and timing of any future commercialization, collaboration, licensing, partnering or other arrangements that we may establish;

•the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;

•the extent to which we in-license or acquire other products and technologies; and

•the timing of the qualification of our CMOs' manufacturing facilities.

Until we are able to generate a sufficient amount of net cash inflows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We expect to continue to seek access to the equity and debt capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through commercialization, collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses or other rights on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2023, we had total cash, cash equivalents and short-term investments of $51.7 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. We currently do not hedge our interest rate risk exposure. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate change in interest rates of 100 basis points would not result in a material change in the fair market value of our portfolio.

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

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Atara Biotherapeutics, Inc. and subsidiaries (the "Company" or “Atara”) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders’ equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company’s recurring losses from operations raises substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Commercialization Revenue and Deferred Revenue – Accounting for Out- License Agreement – Refer to Notes 2 and 5 to the Financial Statements

Critical Audit Matter Description

The Company has entered into certain out-license agreements with Pierre Fabre.

During 2021, the Company entered into a Commercialization Agreement with Pierre Fabre Medicament ("Pierre Fabre"). Under the terms of the agreement, the Company granted Pierre Fabre a license to commercialize and distribute Ebvallo in an initial territory and became responsible for manufacturing and supplying Ebvallo to Pierre Fabre, along with related cell selection services.

In 2022, the Company entered into an Amendment Agreement to the Pierre Fabre Commercialization Agreement (the "PF Amendment No. 1"). Under the terms of the PF Amendment No. 1, Atara became entitled to an additional milestone payment in exchange for, among other things, a reduction in: (i) royalties Atara is eligible to receive, and (ii) the price mark up on supply purchased by Pierre Fabre. Additionally, Atara also agreed to extend the time period for provision of certain services to Pierre Fabre under the Pierre Fabre Commercialization Agreement.

In 2023, the Company entered into an amended and restatement Pierre Fabre Commercialization Agreement (the "A&R Commercialization Agreement"). Under the terms of the A&R Commercialization Agreement, the Company granted Pierre Fabre an expanded license to commercialize and distribute Ebvallo in all other countries in the world and remains responsible for manufacturing and supplying Ebvallo to Pierre Fabre, along with related cell selection services until transfer of responsibility to Pierre Fabre.

The Company recognizes revenue on the commercialization agreements with Pierre Fabre as they satisfy their performance obligations and when a customer obtains control of the promised goods or services. The revenue related to the commercialization agreements with Pierre Fabre is recognized within commercialization revenue within the Consolidated Statements of Operations and Comprehensive Loss. As of December 31, 2023, the Company recognized $7.89 million of commercialization revenue and deferred revenue amounted to $115.4 million, of which $77.8 million is included in current liabilities and $37.6 million is included in long-term liabilities.

We identified accounting for the commercialization agreements, the revenue recognized, and the estimated deferred revenue to be recognized as revenue as a critical audit matter. Given the judgments necessary to determine the accounting literature to apply to a commercialization agreement, the method to estimate and measure the progress toward the completion of the performance obligations and the estimated contractual term over which the performance obligations would be completed, auditing such judgments and estimates required extensive audit effort due to the complexity of the commercialization agreements and the high degree of auditor judgment applied when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to determining the accounting literature to apply to the agreements, assessing management's method for measuring progress and evaluating management's estimation of the contract term over which the performance obligations will be completed included the following, among others:

- We tested the operating effectiveness of controls over commercialization revenue, including those related to the evaluation of contract modifications, identification of performance obligations and the determination of the timing and amount of revenue recognized.
- We reviewed and obtained an understanding of the Company's revenue generating agreements and related transactions during and at the end of the year via review of internal and external presentations, news and publications, and discussions with management.
- We evaluated the Company's conclusions related to the accounting for contract modifications.
- We evaluated management's determination that the agreements are within the scope of ASC 606 - Revenue from Contracts with Customers.
- We evaluated management's determination of the contractual term and the appropriateness of management's method to measure its progress over that term.

- We evaluated the assumptions used in the estimates of total costs and the estimated measure of progress for recognizing revenues by:
  - Performing corroborating inquiries with the Company's project and business development managers, and comparing the assumptions used in the estimates to management's work plans, cost estimates and costs reported to date, and material rights allocated, accumulated and earned.
  - Comparing costs incurred for activities completed to date to the costs forecasted for those activities.
  - Comparing material rights accumulated and earned for activities completed to date to the fulfilment of performance obligations forecasted for those activities.
  - Testing the mathematical accuracy of management’s revenue and current and long-term deferred revenue balances based on the estimated revenue to be recognized over time.

/s/ *DELOITTE & TOUCHE LLP*

San Francisco, California
March 28, 2024

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

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 25,841	$ 92,942
Short-term investments	25,884	149,877
Restricted cash	146	146
Accounts receivable	34,108	40,221
Inventories	9,706	1,586
Other current assets	6,184	10,308
Total current assets	101,869	295,080
Property and equipment, net	3,856	6,300
Operating lease assets	54,935	68,022
Other assets	4,844	7,018
Total assets	$ 165,504	$ 376,420
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,684	$ 6,871
Accrued compensation	11,519	17,659
Accrued research and development expenses	17,364	24,992
Deferred revenue	77,833	8,000
Other current liabilities	31,826	21,394
Total current liabilities	142,226	78,916
Deferred revenue – long-term	37,562	77,000
Operating lease liabilities – long-term	45,693	58,064
Liability related to the sale of future revenues – long-term	34,623	30,236
Other long-term liabilities	4,631	5,564
Total liabilities	264,735	249,780
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Common stock—$0.0001 par value, 500,000 shares authorized as of December 31, 2023 and 2022, respectively; 106,447 and 95,927 shares issued and outstanding as of December 31, 2023 and 2022, respectively	11	10
Additional paid-in capital	1,870,112	1,821,721
Accumulated other comprehensive (loss) income	(204)	(2,067)
Accumulated deficit	(1,969,150)	(1,693,024)
Total stockholders' equity (deficit)	(99,231)	126,640
Total liabilities and stockholders' equity (deficit)	$ 165,504	$ 376,420

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2023	2022
Commercialization revenue	$ 7,886	$ —
License and collaboration revenue	687	63,573
Total revenue	8,573	63,573
Costs and operating expenses:		
Cost of commercialization revenue	8,886	—
Research and development expenses	224,785	272,533
General and administrative expenses	50,908	71,553
Total costs and operating expenses	284,579	344,086
Loss from operations	(276,006)	(280,513)
Other income (expense), net:		
Interest income	5,426	3,059
Interest expense	(5,285)	(373)
Gain on sale of ATOM Facility (See Note 7)	—	50,237
Other income (expense), net:	(246)	(700)
Total other income (expense), net	(105)	52,223
Loss before provision for income taxes	(276,111)	(228,290)
Provision for income taxes	15	12
Net loss	$ (276,126)	$ (228,302)
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities	1,863	(1,699)
Comprehensive loss	$ (274,263)	$ (230,001)
Basic and diluted net loss per common share	$ (2.61)	$ (2.24)
Basic and diluted weighted-average shares outstanding	105,912	101,990

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance as of January, 1 2022	91,671	9	1,744,695	(368)	(1,464,722)	279,614
Issuance of common stock through ATM facilities, net of commissions and offering costs of $517	1,619	—	21,891	—	—	21,891
RSU settlements, net of shares withheld	2,204	1	(624)	—	—	(623)
Issuance of common stock pursuant to employee stock awards	433	—	1,921	—	—	1,921
Stock-based compensation expense	—	—	53,838	—	—	53,838
Net loss	—	—	—	—	(228,302)	(228,302)
Unrealized gain (loss) on available-for-sale securities	—	—	—	(1,699)	—	(1,699)
Balance as of December 31, 2022	95,927	10	1,821,721	(2,067)	(1,693,024)	126,640
Issuance of common stock through ATM facilities, net of commissions and offering costs of $351	3,038	1	2,171	—	—	2,172
Exercise of pre-funded warrants	2,916	—	—	—	—	—
RSU settlements, net of shares withheld	3,670	—	(94)	—	—	(94)
Issuance of common stock pursuant to employee stock awards	896	—	928	—	—	928
Stock-based compensation expense	—	—	45,386	—	—	45,386
Net loss	—	—	—	—	(276,126)	(276,126)
Unrealized gain (loss) on available-for-sale securities	—	—	—	1,863	—	1,863
Balance as of December 31, 2023	106,447	$ 11	$ 1,870,112	$ (204)	$ (1,969,150)	$ (99,231)

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2023	**2022**
Operating activities		
Net loss	$ (276,126)	$ (228,302)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of ATOM Facility	—	(50,237)
Stock-based compensation expense	45,386	53,838
Depreciation and amortization expense	4,829	5,653
Accretion of liability related to sale of future revenues	4,792	—
Non-cash operating lease expense	11,795	8,915
Amortization of investment premiums	792	1,024
Other non-cash items, net	214	147
Changes in operating assets and liabilities:		
Accounts receivable	6,113	(39,235)
Inventories	(8,120)	(1,586)
Other current assets	273	1,836
Other assets	1,043	(266)
Accounts payable	(3,130)	(9,211)
Accrued compensation	(6,140)	(7,491)
Accrued research and development expenses	(3,663)	11,541
Other current liabilities	11,064	2,067
Deferred revenue	30,395	(11,468)
Operating lease liabilities	(12,636)	(8,009)
Other long-term liabilities	142	354
Net cash used in operating activities	(192,977)	(270,430)
Investing activities		
Purchases of short-term investments	(83,648)	(180,589)
Proceeds from maturities and sales of short-term investments	208,712	292,973
Purchases of property and equipment	(1,223)	(4,193)
Proceeds from sale of property and equipment	25	—
Net proceeds from sale of ATOM Facility	—	94,765
Net cash provided by (used in) investing activities	123,866	202,956
Financing activities		
Proceeds from issuance of common stock through ATM facilities, net	2,136	21,891
Proceeds from employee stock awards	928	1,921
Proceeds from sale of future revenues, net	—	30,605
Taxes paid related to net share settlement of restricted stock units	(94)	(623)
Principal payments on finance lease obligations	(947)	(518)
Other financing activities, net	(13)	(192)
Net cash provided by financing activities	2,010	53,084
Increase (decrease) in cash, cash equivalents and restricted cash	(67,101)	(14,390)
Cash, cash equivalents and restricted cash at beginning of period	93,088	107,478
Cash, cash equivalents and restricted cash at end of period	$ 25,987	$ 93,088
Non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and other accrued liabilities	$ 132	$ 61
Accrued costs related to ATM facilities	$ 78	$ —
Proceeds from issuance of common stock through ATM facilities not yet received	$ 114	$ —
Accrued transaction costs related to sale of future revenues	$ —	$ 332
Supplemental cash flow disclosure		
Cash paid for interest	$ 447	$ 335
Cash paid for income taxes	$ 2	$ 19

See accompanying notes to the 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 leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr Virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune disease.

We have several T-cell immunotherapies in clinical development and are progressing multiple next-generation allogeneic chimeric antigen receptor T-cell (CAR T) programs. Our most advanced T-cell immunotherapy program, tab-cel® (tabelecleucel), has received marketing authorization approval under the proprietary name Ebvallo™ by the European Commission (EC) for commercial sale and use in the European Union (EU) and by the Medicines and Healthcare products Regulatory Agency (MHRA) for commercial sale and use in the United Kingdom (UK). Tab-cel is currently in Phase 3 development in the US. In October 2021, we entered into a commercialization agreement (Pierre Fabre Commercialization Agreement) with Pierre Fabre Medicament (Pierre Fabre), as amended in September 2022, pursuant to which we granted to Pierre Fabre an exclusive, field-limited license to commercialize and distribute Ebvallo in Europe and select emerging markets in the Middle East, Africa, Eastern Europe and Central Asia (the Initial Territory), following regulatory approval. In October 2023, we amended and restated the Pierre Fabre Commercialization Agreement (A&R Commercialization Agreement). Pursuant to the A&R Commercialization Agreement, Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute Ebvallo are expanded to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations. See Note 5 for further information. In December 2022, we sold a portion of our right to receive royalties and certain milestones in Ebvallo under the Pierre Fabre Commercialization Agreement to HCR Molag Fund L.P. (HCRx) for a total investment amount of $31.0 million, subject to a repayment cap between 185% and 250% of the total investment amount by HCRx. See Note 6 for further information.

We have licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center (MSK), rights related to our next-generation CAR T programs from MSK, and rights to know-how and technology from the Council of the Queensland Institute of Medical Research (QIMR Berghofer). See Note 8 for further information.

In January 2022, we entered into an asset purchase agreement with FUJIFILM Diosynth Biotechnologies California, Inc. (FDB) and, for certain limited purposes, FUJIFILM Holdings America Corporation, to sell all of the Company's right, title and interest in and to certain assets related to the Atara T-Cell Operations and Manufacturing facility (ATOM Facility) located in Thousand Oaks, California for $100 million in cash, subject to potential post-closing adjustments pursuant to the asset purchase agreement (the Fujifilm Transaction). The closing of the Fujifilm Transaction occurred on April 4, 2022, at which time 136 of our ATOM Facility employees transitioned to FDB as part of the transaction. We also entered into a Master Services and Supply Agreement and related Statements of Work with FDB (collectively, the Fujifilm MSA) which became effective upon the closing and could extend for up to ten years. Pursuant to the Fujifilm MSA, FDB will supply us with specified quantities of our cell therapy product candidates and any products approved by regulatory authorities, manufactured in accordance with cGMP standards. See Note 8 for further information.

In November 2023, we announced a reduction in force that reduced our workforce by approximately 30%. We recognized $6.7 million in total for severance and related benefits for employees laid off under the reduction in force. These charges are one-time termination benefits and are all cash charges. Refer to Note 9 for further information.

Certain prior year amounts, which are not material, have been reclassified to conform to current year presentation in the consolidated statements of operations and comprehensive income (loss) and the notes to consolidated financial statements.

2.Summary of Significant Accounting Policies

Principles of Consolidation

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

Segment and Geographic Information

We operate and manage our business as one operating and reportable segment, which is the business of developing 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.

All commercialization and collaboration revenue recognized in 2023 related to our agreements with Pierre Fabre, a French company. Of the $63.6 million license and collaboration revenue recognized in 2022, $61.8 million related to our agreements with Bayer, a German company, and $1.8 million related to our agreements with Pierre Fabre, a French company.

Use of Estimates

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP), which requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. The level of uncertainty in estimates and assumptions increases with the length of time until the underlying transactions are completed. Significant estimates and assumptions relied upon in preparing these financial statements include those related to revenue recognition, accrued research and development expenses, stock-based compensation expense, liability related to the sale of future revenues and income taxes. Additionally, we use available market information to assess the fair value of our short-term investments. Actual results could differ materially from those estimates. If actual amounts differ from estimates, we include the updates in our consolidated results of operations in the period the actual amounts become known. Historically, the aggregate differences, if any, between our estimates and actual amounts in any year have not had a material effect on our consolidated financial statements.

Liquidity Risk

We have incurred significant operating losses since inception and have relied primarily on public and private equity financings and receipts from commercialization and license and collaboration agreements to fund our operations. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve sustained operating cash inflows or profitability.

Going Concern

We have incurred operating losses since inception and we expect that existing cash, cash equivalents and short-term investments as of December 31, 2023, will not be sufficient to fund our planned operations for at least 12 months after the issuance of the accompanying consolidated financial statements. Although we anticipate the receipt of certain payments from the amended and restated Pierre Fabre Commercialization Agreement in 2024 and 2025, such payments are contingent upon the successful filing and approval of the tab-cel BLA, as well as the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private security offerings; use of our ATM facility as described in Note 9; and/or strategic transactions. We may also need to raise additional funding as required based on the status of our development programs and our projected cash flows. Although we have been successful in raising capital in the past, and expect to continue to raise capital as required, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we are unable to obtain sufficient funding on acceptable terms, we could be forced to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates, which could have a material adverse effect on our business, results of operations, and financial condition. Accordingly, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Concentration of Credit Risk and Other Uncertainties

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

Currency Translation

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, 2023 were not material.

Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents are defined as highly liquid investments with original maturities of 90 days or less at the date of purchase.

Investments with original maturities of greater than 90 days are classified as short-term investments on the balance sheet.

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 recorded to interest income in the consolidated statements of operations and comprehensive loss.

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

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.

Accounts Receivable, net

Accounts receivable are recorded net of estimates of variable consideration for which reserves are established and which result from discounts and chargebacks that are offered within contracts between us and a limited number of specialty pharmacies and a specialty distributor in the United States. These reserves are classified as reductions of accounts receivable.

We estimate the allowance for doubtful accounts using the current expected credit loss model, or CECL model. Under the CECL model, the allowance for doubtful accounts reflects the net amount expected to be collected from the accounts receivable. We evaluate the collectability of these cash flow based on the asset's amortized cost, the risk of loss even when that risk is remote, losses over an asset's contractual life, and other relevant information available to us. Accounts receivable balances are written off against the allowance when it is probable that the receivable will not be collected. Given the nature and history of our accounts receivable, we determined that an allowance for doubtful accounts was not required for the periods presented.

Inventories

Inventories are stated at the lower of cost or estimated net realizable value, on a specific identification basis. We use actual costs to determine our cost basis for inventories. Inventories consist of raw materials, work-in-process and finished goods.

We begin capitalizing costs as inventory when the product candidate receives regulatory approval and when the manufacturing facility producing such inventory is qualified by the relevant regulatory agency. Prior to regulatory approval and qualification, we record such production costs related to product candidates as research and development expenses. Any manufactured product that is available for commercial sale is recorded to inventory; to the extent it is later used for clinical studies, such inventory costs are then recorded within research and development expenses.

We periodically assess the recoverability of our inventory and reduce the carrying value of the inventory when items are determined to be obsolete, defective or in excess of forecasted sales requirements. Inventory write-downs for excess, defective and obsolete inventory are recorded as a cost of sales.

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, except for leasehold improvements, which are depreciated on a straight-line basis over the lesser of the estimated useful life of the leasehold improvement or the lease term. 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. 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.

Asset Retirement Obligation (ARO)

An ARO is a legal obligation 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, we record 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. We derecognize ARO liabilities when the related obligations are settled.

Leases

We determine if a contract is or contains a lease at contract inception. Operating leases are included in operating lease assets, other current liabilities, and operating lease liabilities on our consolidated balance sheets. Our policy is to not recognize right-of-use (ROU) assets and lease liabilities for short-term operating leases with terms of 12 months or less; we recognize short-term lease expense for these leases on a straight-line basis over the lease term. Long-term operating lease ROU assets and long-term operating lease liabilities are presented separately and operating lease liabilities payable in the next twelve months are recorded in other current liabilities. Finance lease ROU assets are recorded in other assets and the related finance lease liabilities are presented in other current liabilities and other long-term liabilities.

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

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

We are considered the sub-lessor for certain of our leases where we have entered into a sub-lease agreement with or have assigned our lease to another party. Rental income was not material for any period presented and we record rental income as a reduction to rent expense within operating expenses.

We analyze whether or not amendments to existing leases classify as a lease modification or a full or partial termination of the existing lease. To the extent a partial lease termination is identified, our accounting policy is to decrease the existing right-of-use asset on a basis proportionate to the reduction in lease liability resulting from the partial termination.

Accruals of Research and Development Costs

We record accruals for estimated research and development costs 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 internal 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 asset and recognized as expense as the services are provided.

Sale of Future Revenues

To the extent that we account for the sale of future revenues as debt in accordance with ASC 470, we amortize the liability and recognize interest expense related to the sale of future revenues using the effective interest rate method over the estimated life of the underlying agreement. The liability and related interest expense are based on our current estimate of expected future payments over the life of the arrangement. We re-assess the amount and timing of expected payments each reporting period using a combination of internal projections and forecasts from external resources and record interest expense on the carrying value of the liability using the imputed effective interest rate on a prospective basis.

Revenue Recognition

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

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

The transaction price is determined based on the consideration to which we will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment, which is discussed in further detail for our out-license agreements in Note 5. Our out-license agreements do not contain a significant financing component.

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

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

As discussed in further detail in Note 5, the terms of our customer contracts include potential payments to us for some or all of the following: nonrefundable, upfront fees; development, regulatory, and commercial milestone payments; research and development funding payments; royalties on the net sales of licensed products; and transition plan cost reimbursements for certain development, safety, regulatory, and process science services. These payments relate to promised goods or services for which revenue will be recognized upon our satisfaction of the underlying performance obligations.

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

Upfront payments: Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we have satisfied our obligations under these arrangements.

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

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

Transition plan cost reimbursements: Reimbursements for certain development, safety, regulatory and manufacturing services are recorded as revenue as we perform the services and related obligations identified within the transition plans for our customers.

Certain judgments affect the application of our revenue recognition policy. For example, we record short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months, and long-term deferred revenue consists of amounts that we expect will be recognized after the next 12 months. This estimate is based on forecasted patient demand, our current operating plan and expected dates of technology transfer, and if these items should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

Cost of commercialization revenue

Cost of commercialization revenue consists primarily of expenses associated with cell selection services performed for Pierre Fabre, in-license sales-related milestone costs, period manufacturing expenses and adjustments to reduce inventory to the lower of cost or net realizable value. Costs incurred to produce Ebvallo prior to regulatory approval, referred to as zero cost inventories, have been recorded as research and development expense in our consolidated statement of operations and comprehensive income (loss). All tab-cel (Ebvallo) sold to Pierre Fabre in the year ended December 31, 2023 was zero cost inventories. Once we begin selling Ebvallo produced after receiving regulatory approval and in a qualified manufacturing facility, and as revenue is recognized on such Ebvallo sales, cost of commercialization revenue will also include direct and indirect costs related to the production of Ebvallo. Such costs include, but are not limited to, CMO costs, quality testing and validation, materials used in production, and an allocation of compensation, benefits and overhead costs associated with employees involved with production.

In 2023 and 2022, cost of commercialization revenue included adjustments of $6.6 million and $0.0 million, respectively, to write-off of inventories and to reflect them at the lower of cost or net realizable value.

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; expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical and preclinical studies; expense incurred under agreements with contract manufacturing organizations related to acquiring and manufacturing clinical study materials and other supplies to support the manufacture of our product candidates; payments under licensing and research and development agreements; other outside services and consulting costs, and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

Stock-Based Compensation Expense

We account for stock-based compensation expense, including the expense of restricted common stock awards, grants of restricted stock units (RSUs), and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant. The fair value of our RSUs is measured at the closing market price of our common stock on the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model.

In determining the fair value of stock option awards granted, we use the Black-Scholes valuation model and assumptions 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 – In 2021 and 2022, volatility was estimated using an average of Atara's historical volatility and comparable public companies' volatility for similar terms. Beginning in 2023, volatility is based solely on Atara's stock price historical volatility.

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.

For awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and begin to recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. Stock-based compensation expense for awards with time-based vesting criteria is recognized as expense on a straight-line basis over the requisite service period. Stock-based compensation expense for awards with performance and other vesting criteria is recognized as expense under an accelerated graded vesting model. We account for forfeitures of stock-based awards as they occur.

Defined Contribution Plan

We have one qualified 401(k) plan covering all eligible employees. Under the plan, employees may contribute up to the statutory allowable amount for any calendar year. We make matching contributions, equal to 50% of each dollar contributed up to the first 6% of an individual's eligible earnings, up to the annual IRS maximum. For the years ended December 31, 2023 and 2022 we recorded matching contributions of approximately $1.9 million and $2.3 million, respectively.

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, 2023 and 2022. We intend to maintain valuation allowances until sufficient evidence exists to support their reversal.

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

Comprehensive Income (Loss)

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

Recent Accounting Pronouncements

We consider the applicability and impact of any Accounting Standards Updates (ASUs) issued by the Financial Accounting Standards Board (FASB). Other than the ASUs listed below, all other ASUs were assessed and determined to be either not applicable to Atara or are expected to have minimal impact on our consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The amendment requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. Additionally, all disclosure requirements under the guidance are also required for public entities with a single reportable segment. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. We are currently evaluating this ASU to determine its impact on our disclosures.

In December 2023, the FASB issued ASU No. 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires enhancements to certain income tax disclosures, most notably the income tax rate reconciliation and income taxes paid. The amendments are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. We do not expect the adoption of this standard will have a material impact on our disclosures.

Additionally, on March 6, 2024, the Securities and Exchange Commission (SEC) issued Final Rule No. 33-11275, *The Enhancement and Standardization of Climate-Related Disclosures for Investors*. The rule requires registrants to provide climate related disclosures in their annual reports, including, but not limited to, material Scope 1 and Scope 2 GHG emissions (for large accelerated filers and accelerated filers); governance and oversight of material climate-related risks; the material impact of climate risks on the registrant's strategy, business model, and outlook; risk management processes for material climate-related risks; and material climate targets and goals. Based on our current small reporting company and non-accelerated filer status, certain elements of the rule are effective for fiscal years beginning after December 15, 2026, with the remaining requirements effective for fiscal years beginning after December 15, 2027. We will evaluate the SEC rule to determine its impact on our future financial reporting requirements and related disclosures.

3.Net Loss per Common Share

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

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

The following table represents the potential common shares issuable pursuant to outstanding securities as of the dates listed 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,	
	2023	2022
Unvested RSUs	6,261,213	6,698,858
Vested and unvested options	10,706,651	10,336,634
ESPP share purchase rights	185,843	86,782
Total	17,153,707	17,122,274

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, 2023:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	$ 14,376	$ —	$ —	$ 14,376
U.S. Treasury obligations	Level 2	9,928	1	—	9,929
Corporate debt obligations	Level 2	26,089	—	(205)	25,884
Total available-for-sale securities		50,393	1	(205)	50,189
Less: amounts classified as cash equivalents		(24,304)	(1)	—	(24,305)
Amounts classified as short-term investments		$ 26,089	$ —	$ (205)	$ 25,884

As of December 31, 2022:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	$ 78,033	$ —	$ —	$ 78,033
U.S. Treasury obligations	Level 2	63,013	3	(394)	62,622
Government agency obligations	Level 2	8,086	—	(48)	8,038
Corporate debt obligations	Level 2	82,598	4	(1,513)	81,089
Commercial paper	Level 2	996	—	—	996
Asset-backed securities	Level 2	6,343	—	(119)	6,224
Total available-for-sale securities		239,069	7	(2,074)	237,002
Less: amounts classified as cash equivalents		(87,122)	(3)	—	(87,125)
Amounts classified as short-term investments		$ 151,947	$ 4	$ (2,074)	$ 149,877

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

	As of December 31, 2023		As of December 31, 2022	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	$ 50,393	$ 50,189	$ 202,323	$ 201,359
Maturing in one to five years	—	—	36,746	35,643
Total available-for-sale securities	$ 50,393	$ 50,189	$ 239,069	$ 237,002

We considered the current and expected future global economic and market conditions, including, but not limited to, the wars in Ukraine and the Middle East and increased tensions between the U.S. and China, and determined that our investments have not been significantly impacted. As of December 31, 2023, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the available-for-sale securities we hold, and we have no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. For all securities with a fair value less than its amortized cost basis, we determined the decline in fair value below amortized cost basis to be non-credit related and no allowance for losses has been recorded. During the years ended December 31, 2023 and 2022, we did not recognize any impairment losses on our investments.

We have elected the practical expedient to exclude the applicable accrued interest from both the fair value and the amortized cost basis of our available-for-sale securities for purposes of identifying and measuring an impairment. We present accrued interest receivable related to our available-for-sale securities in other current assets, separate from short-term investments, on our consolidated balance sheet. As of December 31, 2023 and 2022, accrued interest receivable was $0.3 million and $0.8 million, respectively. Our accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which we consider to be in the period in which we determine the accrued interest will not be collected by us. We have not written off any accrued interest receivables for the years ended December 31, 2023 and 2022.

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.

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, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 25,841	$ 92,942
Restricted cash – short-term	146	146
Total cash, cash equivalents and restricted cash	$ 25,987	$ 93,088

5.Out-license Agreements

Pierre Fabre Commercialization Agreement

In October 2021, we entered into the Pierre Fabre Commercialization Agreement, pursuant to which, we granted to Pierre Fabre an exclusive, field-limited license to commercialize and distribute Ebvallo in Europe and select emerging markets in the Initial Territory following regulatory approval. In September 2022, we entered into Amendment No. 1 to the Pierre Fabre Commercialization Agreement (the PF Amendment). Under the terms of the PF Amendment, following European Commission approval of Ebvallo for EBV+ PTLD and subsequent filing of the Marketing Authorization Application (MAA) transfer to Pierre Fabre, we are entitled to receive an additional $30 million milestone payment in exchange for, among other things, a reduction in: (i) royalties we are eligible to receive as a percentage of net sales of Ebvallo in the Territory, and (ii) the supply price mark up on Ebvallo purchased by Pierre Fabre. Additionally, we agreed to extend the time period for provision of certain services to Pierre Fabre in the Initial Territory at our cost pursuant to the Pierre Fabre Commercialization Agreement. In December 2022, we sold a portion of our right to receive royalties and certain milestone payments related to Ebvallo in the Initial Territory under the Pierre Fabre Commercialization Agreement to HCRx for a total investment amount of $31.0 million, subject to a repayment cap between 185% and 250% of the total investment amount by HCRx. See Note 6 for further information related to the agreement with HCRx.

In October 2023, we entered into the A&R Commercialization Agreement with Pierre Fabre. Pursuant to the A&R Commercialization Agreement, Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute tab-cel are expanded to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below.

Pierre Fabre paid us an upfront cash payment of $45.0 million for the exclusive license grant for the Initial Territory in the fourth quarter of 2021. In December 2022, we met the contractual right to receive $40.0 million in milestone payments upon certain regulatory milestones, for which the cash was received in January 2023. Subject to the terms of the royalty purchase agreement with HCRx, as described in Note 6, we are entitled to receive an aggregate of up to $308.0 million in remaining milestone payments upon achieving certain regulatory and commercial milestones in addition to double-digit tiered royalties as a percentage of net sales of Ebvallo in the Initial Territory, until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights, or the expiration of all regulatory exclusivity for Ebvallo on a country-by-country basis. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of $20.0 million for the expanded exclusive license grant in the Additional Territory, for which the cash was received in January 2024. We will also be entitled to receive an aggregate of up to $620.0 million in additional payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory. We will be eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel in the Additional Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel on a country-by-country basis.

We have entered into a separate manufacturing and supply agreement with Pierre Fabre for us to manufacture Ebvallo for Pierre Fabre to use in the Initial Territory based on a fixed price through December 31, 2023 and at a price equal to cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab-cel (Ebvallo) in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of: i) all activities relating to the transfer of tab-cel manufacturing, pursuant to the A&R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, through the remainder of the term of the A&R Commercialization Agreement. Pierre and we are to use commercially reasonable efforts to achieve this prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the

first BLA (PF Transfer Date). Prior to the Manufacturing Transition Date, we are responsible for manufacturing and supplying tab-cel (Ebvallo) to Pierre Fabre in the Territory. Without transfer of the manufacturing technology, no other party can manufacture Ebvallo.

Cell selection is the process of identifying the appropriate cell line from available tab-cel inventory to be used for a patient. We are responsible for the performance of cell selection services in the Initial Territory at our cost through the earlier of the PF Transfer Date, June 30, 2025 or a date otherwise agreed to by Pierre Fabre and us. To the extent that the transfer of cell selection technology occurs subsequent to June 30, 2025, we will be responsible for the performance of cell selection services in the Initial Territory at Pierre Fabre's cost until cell selection technology is transferred to Pierre Fabre. Without transfer of the cell selection technology, no other party can provide such services. We are responsible for the performance of cell selection services in the Additional Territory through the earlier of the PF Transfer Date or a date otherwise agreed to by Pierre Fabre and us, at the sole expense of Pierre Fabre.

As part of the Pierre Fabre Commercialization Agreement, we formed a joint steering committee (JSC) with Pierre Fabre that provides oversight, decision making and implementation guidance regarding the commercialization activities, the responsibilities of which has been expanded to cover the incremental scope of the A&R Commercialization Agreement.

During the applicable period specified in the A&R Commercialization Agreement, we will be responsible for various development, safety, process science, and regulatory activities, including obtaining regulatory approval in the United States for tab-cel for EBV-associated post-transplant lymphoproliferative disease. Pierre Fabre will pay us for these services in accordance with the A&R Commercialization Agreement. Pierre Fabre will be responsible, at its cost, for obtaining and maintaining all other required regulatory approvals and for commercialization and distribution of tab-cel in the Additional Territory, including conducting any other clinical study required. We will own any intellectual property rights developed solely by us under the Agreement.

Accounting Analysis

Identification of the Contract

We assessed this arrangement in accordance with ASC 606 and concluded that the promises in the A&R Commercialization Agreement represent transactions with a customer.

Identification of the Promises and Performance Obligations

We identified four performance obligations under the A&R Commercialization Agreement, consisting of the following material promises:

(1)the transfer of intellectual property rights in the form of a license in the Initial Territory, the obligation to participate in the JSC, a material right for purchases associated with the manufacture and supply of Ebvallo and the performance of cell-selection services. We concluded that the individual promises are not distinct because Pierre Fabre cannot benefit from the license without the other services and vice versa, since Pierre Fabre is not capable of carrying out the manufacturing and supply and cell selection services on their own, until the transfer of the related technologies occur. Consequently, these promises represent a single performance obligation, collectively referred to as the Initial Territory Obligation.

(2)the transfer of intellectual property rights in the form of a license in the Additional Territory, the manufacture and supply of tab-cel and the performance of cell-selection services, as well as the promises to transfer the related technologies, and perform certain development, safety and regulatory services. We concluded that the promises are not distinct because Pierre Fabre cannot benefit from the license without the other services and vice versa. Consequently, these promises represent a single performance obligation, collectively referred to as the Additional Territory Obligation.

(3)performance of certain process science services, referred to as the Process Sciences Obligation

(4)the sale of certain intermediate inventory used in the production of tab-cel in existence on the Manufacturing Transition Date, referred to as the Intermediate Inventory Obligation.

Determination of the Transaction Price

Under the Pierre Fabre Commercialization Agreement, we determined that the $45.0 million upfront payment constituted the entire consideration to be included in the transaction price at the outset of the arrangement, and the $40.0 million in development milestones achieved in December 2022 were added to the transaction price upon meeting the related milestone criteria. The remaining potential development and commercial milestone payments that we are eligible to receive were excluded from the transaction price, as the milestone amounts were fully constrained based on the probability of achievement or have not been earned. None of the future royalty and sales-based milestone payments were included in the transaction price, as the potential payments represent sales-based

consideration. We will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, as necessary, we will adjust our estimate of the transaction price.

Upon the effective date of the A&R Commercialization Agreement, the $20.0 million additional upfront payment received and estimated revenue for the development, safety, regulatory and process science services were added to the transaction price. The remaining potential development and commercial milestone payments that we are eligible to receive were excluded from the transaction price, as the milestone amounts were fully constrained based on the probability of achievement or have not been earned. None of the future royalty and sales-based milestone payments were included in the transaction price, as the potential payments represent sales-based consideration. Any consideration associated with the Intermediate Inventory Obligation was excluded from the transaction price as the amount was fully constrained based on uncertainty surrounding available inventory on the Manufacturing Transition Date.

We will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, as necessary, we will adjust our estimate of the transaction price.

Allocation of the Transaction Price to Performance Obligations

The transaction price was allocated to each performance obligation based on their relative standalone selling price. We developed the estimated standalone selling price for each of the A&R Commercialization Agreement performance obligations with the objective of determining the price at which we would sell such an item if it were to be sold regularly on a standalone basis.

Recognition of Revenue

Commercialization revenue associated with the Initial Territory Obligation will be recognized over the period during which the material right exists, which would end upon the Manufacturing Transition Date. Based on these considerations and our forecast of the timing and associated costs of the purchases related to the manufacture and supply of Ebvallo and estimated timing of technology transfer, we estimate the material right in the Initial Territory will exist for approximately one to two years. We reassess this evaluation each reporting period. Commercialization revenue associated with sales of Ebvallo to Pierre Fabre under the Initial Territory Obligation is deferred until we have performed the associated cell selection services, or once cell selection technology transfer to Pierre Fabre has been complete. At that point, Pierre Fabre would be able to utilize the Ebvallo it had purchased from us on its own.

Commercialization revenue associated with the Additional Territory Obligation and the Process Sciences Obligation will be recognized using a cost-based input method based on the amount of actual costs incurred relative to the total budgeted costs expected to be incurred for the respective performance obligations. A cost-based input method of revenue recognition requires us to make estimates of costs to complete our performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete our performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. We expect to recognize revenue associated with the Additional Territory Obligation and the Process Sciences Obligation over a period of approximately two years. We reassess this evaluation each reporting period. The transfer of control occurs over the respective time period and, in our judgment, is the best measure of progress towards satisfying the performance obligation. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods. We expect to recognize revenue associated with the Intermediate Inventory Obligation at a point in time on the Manufacturing Transition Date, which is when title and risk of loss, and thus, control, of the intermediate inventory transfers to Pierre Fabre.

Deferred revenue activity related to commercialization revenue for the year ended December 31, 2023 was as follows:

		Total (in thousands)
Deferred revenue, December 31, 2022	$	85,000
Additions		38,170
Recognized into commercialization revenue		(7,775)
Deferred revenue December 31, 2023		115,395
Less: deferred revenue – current portion		(77,833)
Deferred revenue – long-term, December 31, 2023	$	37,562

During the year ended December 31, 2023, we recognized $5.0 million of revenue that was included in the deferred revenue balance as of December 31, 2022.

Costs incurred relating to performing the services within the Additional Territory Obligation and Process Sciences Obligation consist of third party expenses and for time incurred by our employees to satisfy requirements set forth by the A&R Commercialization Agreement. These costs are included in research and development expenses in the consolidated statements of operations and comprehensive income (loss) during the year ended December 31, 2023. Such costs were not material for the year ended December 31, 2023.

Under the A&R Commercialization Agreement, we conduct an early access program observational study at the sole cost and expense of Pierre Fabre. We recognize the costs incurred associated with this study within research and development expenses, which is directly offset by revenue recorded within license and collaboration revenue. The license and collaboration revenue associated with the early access program for the year ended December 31, 2023 was $0.7 million, as compared to $1.8 million for the year December 31, 2022.

Bayer Agreements

In December 2020, we entered into a research, development and license agreement (Bayer License Agreement) with Bayer AG (Bayer) pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271 (the Licensed Products).

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

In March 2021, we entered into a Technology Transfer Agreement with Bayer (the Bayer Tech Transfer Agreement), which was contemplated as part of the Bayer License Agreement, to transfer to Bayer the ATA3271 manufacturing process being developed as part of the CMC services in the Bayer License Agreement.

In March 2021, we also entered into a Manufacturing and Supply Agreement with Bayer (the Bayer Manufacturing Agreement), which was contemplated as part of the Bayer License Agreement, to manufacture Phase 1 and 2 allogeneic mesothelin-directed CAR T-cell therapies for Bayer to use in clinical trials at a price based on our costs plus a reasonable margin, which is consistent with our standalone selling price. Collectively, the Bayer License Agreement, the Manufacturing and Supply Agreement and the Technology Transfer Agreement are referred to as "the Bayer Agreements".

In May 2022, Bayer notified us of its decision to terminate the Bayer Agreements, and on August 2, 2022, we entered into the Termination, Amendment and Program Transfer Agreement with which terminated the Bayer Agreements (the Bayer Termination Agreement) with an effective date of July 31, 2022. Upon the termination effective date, full product development and commercialization rights related to ATA2271 and ATA3271 reverted to Atara. In return for certain activities performed by Atara prior to the termination effective date, Bayer paid Atara $4.2 million in September 2022. Utilizing the cost-based input method, we recognized license and collaboration revenue of $61.8 million for 2022. As a result of the termination, no license and collaboration revenue related to the Bayer Agreements was recognized for the year ended December 31, 2023, and there was no deferred revenue related to the Bayer Agreements as of December 31, 2023 or December 31, 2022.

6.Liability Related to the Sale of Future Revenues

In December 2022, we entered into a Purchase and Sale Agreement (the HCRx Agreement) with HCR Molag Fund, L.P., a Delaware limited partnership, (HCRx). In exchange for a payment of $31.0 million (the Investment Amount) to Atara, net of certain transaction expenses, HCRx obtained the right to receive certain Ebvallo royalties and milestone payments payable by Pierre Fabre under the Pierre Fabre Commercialization Agreement up to an agreed upon multiple of the Investment Amount.

Under the HCRx Agreement, HCRx is entitled to receive tiered royalties on net sales of Ebvallo in the Initial Territory in amounts ranging from the mid-single digits to double digits based on annual net sales. HCRx is also entitled to certain milestone payments due to Atara from Pierre Fabre. The total royalties and milestones payable to HCRx are capped between 185% and 250% of the Investment Amount, depending upon the timing of such royalties and milestones. Upon meeting the cap amount, HCRx's right to receive royalties and milestone payments will terminate and all rights will revert to Atara. To the extent a certain milestone within the

Pierre Fabre Commercialization Agreement is not achieved on or prior to June 30, 2026, we will be required to make a one-time cash payment in the amount of $9.0 million to HCRx, and HCRx shall transfer all of its right, title and interest in this certain $9.0 million milestone payment to Atara. This payment, if required, would be included in the calculation of aggregate payments made to HCRx.

The gross proceeds of the Investment Amount of $31.0 million were recorded as a liability related to the sale of future revenues, net of transaction costs of $0.4 million, and is be amortized using the effective interest method over the life of the arrangement.

To determine the amortization of the recorded liability, we are required to estimate the total amount of future payments to be received by HCRx. The sum of these amounts less the $31.0 million proceeds we received will be recorded as interest expense over the life of the HCRx Agreement. We will estimate the effective interest rate used to record non-cash interest expense under the HCRx Agreement based on the estimate of future royalty payments to be received by HCRx. As of December 31, 2023, the annual effective interest rate was approximately 12%. Over the life of the arrangement, the actual effective interest rate will be affected by the amount and timing of the actual and forecasted royalty and milestone payments to HCRx. At each reporting date, we reassess our estimate of the timing and amounts of future payments made to HCRx, and prospectively adjust the effective interest rate and amortization of the liability as necessary.

The following table presents the changes in the liability related to the sale of future revenues under the HCRx Agreement for the year ended December 31, 2023:

		(in thousands)
Liability related to sale of future revenues as of December 31, 2022	$	30,236
Accretion of interest expense on liability related to sale of future revenues		4,792
Amortization of debt discount and debt issuance costs		79
Repayment of the liability		(31)
Liability related to sale of future revenues as of December 31, 2023		35,076
Less: current portion classified within other accrued liabilities		(453)
Long-term liability related to sale of future revenues	$	34,623

7.Sale of ATOM Facility

On April 4, 2022, we completed the sale of the ATOM Facility to FDB for net proceeds of $94.8 million, after deducting transaction costs of $4.6 million and other adjustments to the purchase price. The sale resulted in a gain of $50.2 million included within other income (expense), net for the year end December 31, 2022. As disclosed in Note 8, although we have assigned the lease for the ATOM Facility to FDB, we have not received novation from the landlord. Therefore, the lease-related assets and liabilities for the ATOM Facility remain on our balance sheet. Refer to the summary of assets sold and gain on sale of the ATOM Facility:

(in thousands)		
Net proceeds from sale of ATOM Facility	$	94,765
Assets sold:		
Other current assets	$	190
Property and equipment, net		44,299
Other assets		39
Less: Assets sold		44,528
Gain on sale of ATOM Facility	$	50,237

In connection with the sale, we entered into a Transition Services Agreement (TSA) with FDB, pursuant to which we assisted FDB in the transition of certain functions, including, but not limited to, information technology, finance and technical operations. FDB reimbursed us at cost for all third party expenses incurred in conjunction with the TSA and for time incurred by our employees to satisfy requirements set forth by the TSA. The reimbursements are recorded as reductions to the related Operating expenses and the amounts associated with reimbursements for employee time incurred were not material for the years ended December 31, 2023 and 2022. The TSA was terminated in March 2023.

8.Leases

We lease office space for our corporate headquarters in Thousand Oaks, California. In November 2018, we entered into a lease agreement for this office space that expires in February 2026 and for which we have the option to extend the lease for an additional period of five years after the initial term.

In March 2021, we entered into a new lease agreement for approximately 33,659 square feet of office, lab and warehouse space in Thousand Oaks, California. During the third quarter of 2021, the initial 10.5-year lease term commenced, upon substantial completion of the landlord's work as defined under the agreement. Base rent is subject to annual increases of 3% with each annual anniversary of the rent commencement date. We have the option to extend this lease for two additional five-year periods after the initial term. Additionally, in 2021, we entered into an amended lease agreement for our office and lab space in Aurora, Colorado, to add additional lab space.

In November 2023, we entered into an amended lease agreement for our office and lab space in Aurora, Colorado, to extend the term of the lease agreement to April 2025.

In February 2017, we entered into a lease agreement (the ATOM Lease) 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 headlease commenced on February 15, 2018, upon the substantial completion of landlord's work as defined under the agreement. In April 2022, we assigned the ATOM Lease to FDB in connection with the closing of the sale of the ATOM Facility to FDB. Under ASC 842, we are considered to be the sub-lessor of the ATOM Lease. We have not received novation from the landlord and therefore have not been relieved of our primary obligations under the headlease. Therefore, the ROU asset and lease liability for the ATOM Facility remain on our balance sheet.

We evaluated our vendor contracts to identify embedded leases and determined that the Fujifilm MSA contained items that constituted a lease under ASC 842, Leases, as Atara has the right to substantially all of the economic benefits from the use of the asset and can direct the use of the asset. We concluded that the Fujifilm MSA contains an embedded operating lease for certain dedicated processing rooms for the manufacturing of Atara product and an embedded finance lease for certain freezers dedicated for our use. The Fujifilm MSA includes contractual obligations in the form of payments for the processing rooms and the freezers, each over a term of five years. As a result, we added ROU assets and lease liabilities for the processing rooms and freezers for the initial term of the lease in the amounts of $50.8 million and $4.8 million, respectively. In November 2023, we agreed to forego the use of one processing room for approximately one year in return for a reduction in contractual obligations under the Fujifilm MSA. We have the option to subsequently reclaim the processing room or release it to FDB for the remainder of the initial term.

We lease office space in South San Francisco, California under a non-cancellable lease agreement. In December 2021, we entered into a second amendment with the landlord to extend the lease term through May 2025. The amended lease agreement does not include an option to extend the lease term. In connection with the amended lease, we are required to maintain a letter of credit in the amount of $0.1 million to the landlord. In October 2022, we entered into a sub-lease agreement with a third party for this office space. The sub-lease term commenced in November 2022 and expires in May 2025, with no option to extend the sub-lease term. We have not received novation from the landlord and therefore have not been relieved of our primary obligations under the headlease. Therefore, the ROU asset and lease liability for the South San Francisco office remain on our balance sheet.

The maturities of lease liabilities under our operating and finance leases as of December 31, 2023 were as follows:

	Operating Leases	Finance Leases
Years Ending December 31,	(in thousands)	
2024	$ 17,209	$ 1,219
2025	18,486	1,263
2026	17,271	1,285
2027	5,760	436
2028	3,319	—
Thereafter	12,459	—
Total lease payments	$ 74,504	$ 4,203
Less: amount representing interest	(17,547)	(673)
Present value of lease liabilities	$ 56,957	$ 3,530
Balance as of December 31, 2023		
Other current liabilities	$ 11,264	$ 915
Operating lease liabilities – long-term	45,693	—
Other long-term liabilities	—	2,615
Total	$ 56,957	$ 3,530

The components of lease cost were as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
	(in thousands)	
Operating lease cost:		
Operating lease cost	$ 17,192	$ 14,245
Short-term lease cost	201	386
Total operating lease cost	$ 17,393	$ 14,631
Finance lease cost:		
Amortization expense	$ 976	$ 872
Interest on lease liabilities	416	373
Total finance lease cost	$ 1,392	$ 1,245

Other information related to leases was as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
	(in thousands, except lease term and discount rate)	
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 16,660	$ 13,417
Operating cash flows for finance leases	416	335
Financing cash flows for finance leases	947	518
Operating lease assets obtained in exchange for lease obligations:	$ 312	$ 50,779
Finance lease assets obtained in exchange for lease obligations:	—	4,795
Non-cash (decrease) increase to operating lease assets due to remeasurement of lease liabilities:	(1,589)	—
Weighted Average Remaining Lease Term		
Operating leases	5.2 years	5.9 years
Finance leases	3.3 years	4.2 years
Weighted Average Discount Rate		
Operating leases	11.4 %	9.9 %
Finance leases	10.4 %	10.4 %

Asset Retirement Obligation

Our asset retirement obligation (ARO) consists of a contractual requirement to remove the tenant improvements at the ATOM Facility in Thousand Oaks, California and restore the facility to a condition specified in the lease agreement. Although we assigned the ATOM Lease to FDB in connection with the closing of the sale of the ATOM Facility to FDB in April 2022, we have not received novation from the landlord. Therefore, the ARO associated with the ATOM Facility remains on our balance sheet. We recorded an estimate of the fair value of our ARO liability in other long-term liabilities and the ARO asset as a long-term asset in the period incurred. The fair value of the ARO asset is amortized over the lease term. The fair value of our ARO was estimated by discounting projected cash flows over the estimated life of the related assets using our credit adjusted risk-free rate. As of December 31, 2023 and December 31, 2022, the ARO asset and liability were not material.

9.Restructuring

On August 8, 2022 we announced a strategic reduction in workforce of approximately 20% to focus our activities as an organization centered on research and development. The workforce reduction included total restructuring charges of $6.0 million, comprised primarily of severance payments, wages for the 60-day notice period in accordance with the California Worker Adjustment and Retraining Notification (WARN) Act and continuing health care coverage for a period of time after separation. In most cases, the severance payments were paid as a lump sum in October 2022. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits were paid between October 2022 and November 2023, and there are no further payments required for this reduction in workforce as of December 31, 2023. All of the costs were cash expenditures and represented one-time termination benefits.

On November 1, 2023 we announced a strategic reduction in workforce of approximately 30%. The workforce reduction resulted in total restructuring charges of $6.7 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance payments were paid as a lump sum in January 2024. All of the costs are cash expenditures and represent one-time termination benefits.

The following is a summary of restructuring charges associated with the reductions in force for the periods presented:

	Year Ended December 31, 2023	Year Ended December 31, 2022
	(in thousands)	
Research and development expense	$ 5,619	$ 2,544
General and administrative expense	1,111	3,420
Total restructuring charges	$ 6,730	$ 5,964

The following restructuring liability activity was recorded in connection with the reduction in force for the year ended December 31, 2023, with all of the $4.9 million liability balance as of December 31, 2023 included within other current liabilities on the accompanying consolidated balance sheet:

	Year ended December 31, 2023	Year ended December 31, 2022
	(in thousands)	
Liability balance, January 1	$ 1,545	$ —
Restructuring charges	6,730	5,964
Cash payments	(3,352)	(4,419)
Liability balance, December 31	$ 4,923	$ 1,545

10.Commitments and Contingencies

MSK Agreements

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

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

In March 2021, we amended and restated our license agreement with MSK to terminate our license to certain rights and license additional know-how rights not otherwise covered by our existing agreements.

QIMR Berghofer Agreements

In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer. Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology that we exercised in June 2018. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019, August 2020 and December 2021, in each case, to terminate our license to certain rights. Our current license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any. Under the terms of our current research and development collaboration agreement, we are also required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. These payments are expensed on a straight-line basis over the related development periods. The agreement also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones.

Other In-license and Collaboration Agreements

From time to time, we have entered into other license and collaboration agreements with other parties. For example, we licensed rights related to our MSK-partnered next-generation CAR T programs from the National Institutes of Health in December 2018.

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when the underlying milestones are achieved or royalties are earned. Sales related milestone and royalty costs related to Ebvallo are recorded in cost of commercialization revenue, whereas regulatory milestone costs are recorded in research and development expense. As of December 31, 2023 and 2022, there were no material outstanding obligations for milestones and royalties under our in-license and collaboration agreements.

CRL Manufacturing Agreement

In December 2019, we entered into a Commercial Manufacturing Services Agreement (the CRL MSA) with Cognate BioServices, Inc., which was acquired by Charles River Laboratories Inc. (CRL) in March 2021.

Pursuant to the CRL MSA, CRL provides manufacturing services for our product and certain of our product candidates. We further amended the CRL MSA to extend the term until the earlier of March 31, 2024 or upon receipt of certain batches of our product and product candidates. We are currently in negotiations with CRL for a new commercial drug product supply agreement to be effective upon the expiration of the CRL MSA. However, there can be no assurance that we will be able to enter into a new commercial drug product supply agreement with CRL on terms favorable or acceptable to us, or at all. If we are unable to enter into a new commercial drug product supply agreement or extend the CRL MSA, we may need to identify alternative sources of drug product supply.

Fujifilm Master Services and Supply Agreement

In January 2022, we entered into the Fujifilm MSA, which became effective upon the closing of the sale of the ATOM Facility on April 4, 2022 and could extend for up to ten years. Pursuant to the Fujifilm MSA, FDB will supply us with specified quantities of our cell therapy products and product candidates, manufactured in accordance with cGMP standards. We have certain non-cancellable minimum commitments to purchase products and services over the first five years of the Fujifilm MSA. The Fujifilm MSA does not obligate us to purchase products and product candidates exclusively from FDB.

Other Research, Development and Manufacturing Agreements

We may enter into other contracts in the normal course of business with clinical research organizations for clinical trials, with CMOs for product, product candidates and clinical supplies, and with other vendors for preclinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination on notice. As of December 31, 2023 and December 31, 2022, there were no material amounts accrued related to contract termination charges.

Minimum Commitments

The non-cancellable minimum commitments for products and services, subject to agreements with a term of greater than one year with clinical research organizations and CMOs, excluding those recognized on our balance sheet, as of December 31, 2023 are set forth below:

Calendar Year	Remaining Minimum Commitment as of December 31, 2023 (in thousands)
2024	14,085
2025	13,308
2026	9,605
2027	3,388
Total	$ 40,386

We have incurred $19.4 million and $14.2 million against such minimum commitments for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023 and December 31, 2022, we have accrued $11.2 million and $9.2 million in research and development expenses related to minimum purchase commitments.

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we consider the fair value of these indemnification agreements to be minimal. Accordingly, we did not record liabilities for these agreements as of December 31, 2023 and 2022.

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.

11.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, 2023 and 2022.

Equity Offerings

As part of our July 2019 underwritten public offering, we issued and sold pre-funded warrants to purchase 2,945,026 shares of common stock in an underwritten public offering pursuant to a shelf registration on Form S-3.

Each pre-funded warrant entitles the holder to purchase one share of common stock at an exercise price of $0.0001 per share and expires seven years from the date of issuance. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise (the Maximum Ownership Percentage). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. During the year ended December 31, 2023, 361,260 of the July 2019 pre-funded warrants were exercised, and, as of December 31, 2023, pre-funded warrants to purchase 2,527,266 shares of our common stock from the July 2019 offering were outstanding.

In May 2020, we issued and sold pre-funded warrants to purchase 2,866,961 shares of common stock at a public offering price of $11.3199 per warrant in an underwritten public offering pursuant to a shelf registration on Form S-3.

In December 2020, we issued and sold pre-funded warrants to purchase 2,040,816 shares of common stock at a public offering price of $24.4999 per warrant in an underwritten public offering pursuant to a shelf registration on Form S-3.

The terms of the pre-funded warrants issued and sold as part of the 2020 public offerings were similar to those issued and sold in 2019. During the year ended December 31, 2023, 1,898,578 and 656,107 of the May 2020 and December 2020 pre-funded warrants, respectively, were exercised. As of December 31, 2023, 968,383 and 1,384,709 of the pre-funded warrants to purchase shares of our common stock issued and sold as part of the May 2020 and December 2020 underwritten public offerings, respectively, were outstanding.

In January 2024, we issued and sold pre-funded warrants to purchase 27,272,727 shares of common stock at a price of $0.5499 per warrant in a registered direct offering pursuant to a shelf registration on Form S-3. The gross proceeds from this sale were $15.0 million, resulting in net proceeds of $14.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each of the January 2024 pre-funded warrants issued entitles the holder to purchase one share of common stock at an exercise price of $0.0001 per share, with no expiration date. These warrants were recorded as a component of stockholders' equity within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise (Maximum Ownership Percentage). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%.

ATM Facilities

In the past three years, we have entered into two separate sales agreements with Cowen and Company, LLC (Cowen): in November 2021 (the 2021 ATM Facility) and in November 2023 (the 2023 ATM Facility). Each ATM facility provides or provided for the sale, in our sole discretion, of shares of our common stock having an aggregate offering price of up to $100.0 million, through Cowen, as our sales agent. We filed a registration statement on Form S-3 registering the offer and sale of these shares under the Securities Act (the 2023 Registration Statement). Upon the effectiveness of the 2023 Registration Statement, the 2021 ATM Facility was terminated, and no further sales can be made under the 2021 ATM Facility. The issuance and sale of these shares by us pursuant to the ATM facilities are deemed "at the market" offerings defined in Rule 415 under the Securities Act of 1933, as amended (the Securities Act), and were registered under the Securities Act. Commissions of up to 3.0% are due on the gross sales proceeds of the common stock sold under each ATM facility.

During the year ended December 31, 2022, we sold an aggregate of 1,618,672 shares of common stock under the ATM facilities, at an average price of $13.84 per share, for gross proceeds of $22.4 million and net proceeds of $22.0 million, after deducting commissions and other offering expenses payable by us.

During the year ended December 31, 2023, we sold an aggregate of 3,038,432 shares of common stock under the ATM facilities, at an average price of $0.83 per share, for gross proceeds of $2.5 million and net proceeds of $2.2 million, after deducting commissions and other offering expenses payable by us. Approximately $0.1 million of the $2.2 million net proceeds were received on January 2, 2024.

As of December 31, 2023, we had $98.2 million of common stock remaining and available to be sold under the 2023 ATM Facility.

From January 1, 2024 through March 15, 2024, we sold an additional 12,321,365 shares of common stock under the 2023 ATM Facility, at an average price of $0.77 per share, for gross proceeds of $9.5 million and net proceeds of $9.3 million, after deducting commissions and other offering expenses payable by us. As of March 15, 2024, we had $88.7 million of common stock remaining and available to be sold under the 2023 ATM Facility, subject to certain conditions as specified in the agreement.

Equity Incentive Plans

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

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

Under the terms of the 2014 EIP, we may grant stock options, RSAs and RSUs to employees, directors, consultants and other service providers. RSUs generally vest over two to four years. The fair value of RSUs, including those with performance conditions, is determined as the closing stock price on the date of grant. The 2014 EIP expires March 31, 2024, after which no new awards can be granted. All awards granted prior to the 2014 EIP expiration continue to remain outstanding and governed in accordance with the rules set forth in the 2014 EIP and the terms of the associated grant notice.

In February 2018, we adopted the 2018 Inducement Plan (Inducement Plan), under which we may grant options, stock appreciation rights, RSAs and RSUs to new employees. In November 2020, September 2021 and June 2022, we amended the Inducement Plan to reserve an additional 1,500,000 shares of the Company's common stock for issuance under the Inducement Plan in each case.

Stock options are granted with exercise prices at no less than 100% of the 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 fair value of the shares on the date of grant. The estimated fair value of the shares is generally equal to the closing market price of the Company's common stock on the measurement date. Options granted generally vest over two to four years and expire in seven to ten years.

In 2022, we granted performance-based stock options to certain of our employees that provide for the issuance of stock options to purchase common stock if specified Company performance criteria related to business development initiatives are achieved. The number of performance-based awards that ultimately vests depends upon if performance criteria are achieved within a specified timeline, as well as the employee's continuous service, as defined in the 2014 EIP, through the date of vesting. None of the performance criteria were achieved and the awards were subsequently forfeited.

As of December 31, 2023, a total of 20,326,356 shares of common stock were reserved for issuance under the 2014 EIP, of which 5,714,772 shares were available for future grant and 14,611,584 shares were subject to outstanding options and RSUs, including performance-based awards. As of December 31, 2023, 4,773,147 shares of common stock were reserved for issuance under the Inducement Plan, of which 2,397,366 shares were available for future grant and 2,375,781 shares were subject to outstanding options and RSUs.

Restricted Stock Units

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

	RSUs	
	Shares	Weighted Average Grant Date Fair Value
Balance as of December 31, 2022	6,708,608	$ 10.61
Granted	5,635,916	$ 3.57
Forfeited	(2,388,808)	$ 7.91
Vested	(3,688,003)	$ 8.89
Balance as of December 31, 2023	6,267,713	$ 6.32

The weighted average grant date fair value of RSUs granted during the years ended December 31, 2023 and 2022 was $3.57 and $8.26, respectively. The estimated fair value of RSUs that vested in the years ended December 31, 2023 and 2022 was $32.8 million and $34.4 million, respectively. As of December 31, 2023, there was $35.9 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.0 years. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2023 was $3.2 million.

Under our RSU settlement procedures, for some of the RSUs granted to our employees, we withhold shares at settlement to cover the estimated payroll withholding tax obligations. During 2023, we settled 3,688,003 shares underlying RSUs, of which 51,244 shares underlying RSUs were net settled by withholding 18,203 shares. The value of the shares underlying RSUs withheld was $0.1 million, based on the closing price of our common stock on the settlement date. During 2022, we settled 2,247,296 shares underlying RSUs, of which 114,444 shares underlying RSUs were net settled by withholding 43,524 shares. The value of the shares underlying RSUs withheld was $0.6 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:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2022	10,645,555	$ 16.88	6.4	$ 42
Granted	4,693,897	3.64		
Exercised	—	—		
Forfeited or expired	(4,619,801)	15.60		
Balance as of December 31, 2023	10,719,651	$ 11.63	6.5	$ —
Vested and expected to vest as of December 31, 2023	10,719,651	$ 11.63	6.5	$ —
Exercisable as of December 31, 2023	6,389,752	$ 15.40	5.1	$ —

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2023 and the exercise price of outstanding, in-the-money options. As of December 31, 2023, there was $16.6 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 1.9 years. This excludes unrecognized stock-based compensation expense for performance-based stock options that were deemed not probable of vesting in accordance with U.S. GAAP.

No options for shares of our common stock were exercised during the year ended December 31, 2023. Options for 15,989 shares of our common stock were exercised during the year ended December 31, 2022, with an intrinsic value of $0.1 million. As we believe it is more likely than not that no stock option related tax benefits will be realized, we do not record any net tax benefits related to exercised options.

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

	Year ended December 31,	
	2023	2022
Assumptions:		
Expected term (years)	5.80	6.0
Expected volatility	83.9 %	73.2 %
Risk-free interest rate	4.2 %	2.1 %
Expected dividend yield	0.0 %	0.0 %
Fair Value:		
Weighted-average estimated grant date fair value per share	$ 2.62	$ 5.88
Options granted	4,693,897	3,615,971
Total estimated grant date fair value	$ 12,298,010	$ 21,261,909

The estimated fair value of stock options that vested in the years ended December 31, 2023 and 2022 was $17.0 million and $23.2 million, respectively.

Employee Stock Purchase Plan

In May 2014, we adopted the 2014 Employee Stock Purchase Plan ("2014 ESPP"), which became effective on October 15, 2014 upon the pricing of our IPO. The 2014 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Eligible employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the common stock at (i) the beginning of the offering period or (ii) at the end of the purchase period. We recorded $0.7 million and $1.1 million of expense related to the 2014 ESPP in the years ended December 31, 2023 and 2022, respectively. A total of 896,246 and 417,081 shares were purchased under the ESPP during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, there was $0.1 million of unrecognized stock-based compensation expense related to the ESPP that is expected to be recognized by the end of second quarter of 2024.

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, 2023, there were 2,279,049 shares authorized under the 2014 ESPP.

Reserved Shares

The following shares of common stock were reserved for future issuance under our equity incentive plans as of December 31, 2023:

	Total Shares Reserved
2014 Equity Incentive Plan	20,326,356
2018 Inducement Plan	4,773,147
2014 Employee Stock Purchase Plan	10,593
Total reserved shares of common stock	25,110,096

Stock-based Compensation Expense

The following is a summary of stock-based compensation expense for the periods presented:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Research and development	$ 26,529	$ 31,363
General and administrative	18,857	22,475
Total stock-based compensation expense	$ 45,386	$ 53,838

12.Income Taxes

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

	Year Ended December 31,	
	2023	2022
	(in thousands)	
United States	$ (276,360)	$ (228,395)
Foreign	249	105
Total loss before provision for income taxes	$ (276,111)	$ (228,290)

The components of provision for income taxes were as follows in each period presented:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Current provision for income taxes:		
State	$ 1	$ —
Foreign	14	12
Total current provision for income taxes	$ 15	$ 12

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

	Year Ended December 31,	
	2023	2022
Federal income taxes at statutory rate	21.0 %	21.0 %
Research tax credits	4.3 %	7.8 %
Stock-based compensation	(4.5 %)	(3.8 %)
Other	(0.4 %)	(0.2 %)
Change in valuation allowance	(20.4 %)	(24.8 %)
Effective tax rate	0.0 %	0.0 %

Deferred tax assets and liabilities reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and (b) operating loss and tax credit carryforwards. Significant components of our deferred tax assets and liabilities were as follows for each of the dates presented:

	As of December 31,	
	2023	2022
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 323,581	$ 302,591
Capitalized research expenses	72,229	50,522
Tax credit carryforwards	30,580	19,427
Stock-based compensation	14,033	19,201
Deferred revenue	17,018	10,069
Operating lease liabilities	12,035	15,857
License fees	5,926	6,877
Other	11,187	13,169
Total deferred tax assets	486,589	437,713
Valuation allowance	(474,982)	(422,493)
Total deferred tax assets	11,607	15,220
Deferred tax liabilities:		
Operating lease assets	(11,607)	(15,220)
Total deferred tax liabilities	(11,607)	(15,220)
Net deferred tax assets (liabilities)	$ —	$ —

Beginning January 1, 2022, the Tax Cuts and Jobs Act (the Tax Act) eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to Internal Revenue Code (IRC) Section 174. The capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses. As a result of this provision of the Tax Act, deferred tax assets related to capitalized research expenses pursuant to IRC Section 174 increased by $21.7 million and $43.7 million for the years ended December 31, 2023 and 2022, respectively. These increases were partially offset by amortization on research expenses capitalized in prior years.

Our tax credit carryforwards increased by $11.2 million, as compared to 2022, due to research and development and orphan drug credits generated during the current year.

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, 2023 and 2022. 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 $52.5 million for the year ended December 31, 2023 due to the increase in our net deferred tax assets.

In August 2022, the CHIPS and Science Act (CHIPS Act) and the IRA were enacted, neither of which are expected to have a material impact to our financial statements.

The American Rescue Plan Act (ARA) was signed into law on March 11, 2021. We do not expect the ARA to have a material impact on our financial statements, however, given the potential changes to IRC Section 162(m) effective in 2027 as a result of the ARA, we will continue to monitor and assess.

Under the Tax Act, federal NOLs generated in tax years beginning on or after January 1, 2018 may be carried forward indefinitely, but the utilization of such federal NOLs is limited to 80% of taxable income in future years. Since enactment, the IRS and Treasury have issued final and proposed regulations including clarifying guidance on several topics addressed by the Tax Act. Not all states conform to the Tax Act or and other states have varying conformity to the Tax Act.

As of December 31, 2023, for federal income tax purposes, we had NOL carryforwards of approximately $1.1 billion of which $23.3 million begin to expire in 2035 and the remaining may be carried forward indefinitely, research & development tax credits of $34.6 million which begin to expire in 2032, and orphan drug tax credits of $111.8 million which begin to expire in 2035. For state income tax purposes, we had NOL carryforwards of approximately $1.3 billion which begin to expire in 2030, research & development tax credits of $43.5 million which may be carried forward indefinitely, and California Completes tax credit of $2.0 million, which begins to expire in 2025.

Under IRC Section 382, as amended, substantial restrictions exist on the utilization of NOL and tax credit carryforwards in the event a corporation 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. Accordingly, our ability to utilize NOL and tax credit carryforwards may be limited as a result of such ownership changes, and such a limitation could result in the expiration of carryforwards before they are utilized.

We have completed a Section 382 study of transactions in our stock through December 31, 2023. The study concluded that we have experienced ownership changes since inception. However, this is not expected to result in the expiration of tax attribute carryforwards prior to utilization.

The changes in the balance of gross unrecognized tax benefits, which excludes interest and penalties, for the years ended December 31, 2022 and 2023 are as follows:

	(In thousands)
Balance as of January 1, 2022	144,067
Gross increases for tax positions related to current year	7,683
Gross increases for tax positions related to prior year	—
Gross decreases for tax positions related to prior year	(785)
Balance as of December 31, 2022	150,965
Gross increases for tax positions related to current year	5,538
Gross increases for tax positions related to prior year	3,843
Gross decreases for tax positions related to prior year	—
Balance as of December 31, 2023	$ 160,346

We currently have a full valuation allowance against our 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. The reversal of unrecognized tax benefits would not affect our effective tax rate to the extent we continue to maintain a full valuation allowance against our deferred tax assets.

Our policy is to account for interest and penalties related to uncertain tax positions as a component of the income tax provision. We have no accrued interest and penalties as of December 31, 2023 and 2022 due to available tax losses.

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

As of December 31, 2023, we are not permanently reinvested with respect to its foreign earnings and have not recorded deferred income taxes and withholding taxes as these taxes are immaterial to the financial statements.

13.Supplemental Balance Sheet Information

Inventories

Inventories consist of the following as of each period:

	December 31, 2023	December 31, 2022
	(in thousands)	
Raw Materials	$ 2,335	$ 1,214
Work-in-process	7,371	372
Total inventories	$ 9,706	$ 1,586

Property and equipment, net

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Leasehold improvements	$ 904	$ 875
Lab equipment	15,540	14,797
Machinery and equipment	572	572
Computer equipment and software	1,279	1,149
Furniture and fixtures	1,272	1,297
Construction in progress	158	32
Property and equipment, gross	19,725	18,722
Less: accumulated depreciation	(15,869)	(12,422)
Property and equipment, net	$ 3,856	$ 6,300

Depreciation expense was $3.7 million and $4.7 million for the years ended December 31, 2023 and 2022, respectively.

Other current liabilities

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

	December 31, 2023	December 31, 2022
	(in thousands)	
Accrued operating expenses	$ 19,007	$ 7,435
Current portion of operating lease liabilities	11,264	12,806
Current portion of finance lease liabilities	915	834
Other accrued liabilities	640	319
Total other current liabilities	$ 31,826	$ 21,394

14.Subsequent Events

In January 2024, we announced a reduction in force of approximately 25% of total workforce. We expect to recognize approximately $4.5 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2024. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from February 2024 through January 2025. The majority of the associated costs represent cash expenditures.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2023. 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, 2023 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, 2023 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, 2023.

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, 2023, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2023 which were identified in connection with our evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that many of our employees are working remotely. We are continually monitoring and assessing our remote working situation to minimize the impact to the design and operating effectiveness of our internal controls.

Item 9B. Other Information

During the three months ended December 31, 2023, none of the Company's directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not Applicable.

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 2024 annual meeting of stockholders (the Definitive Proxy Statement), pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after December 31, 2023, 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.

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 Accountant Fees and Services

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

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

(a)(2) Financial Statement Schedules.

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

(a)(3) Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	3.2	06/20/2014	
3.2	Second Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	8-K	3.1	09/27/2022	
4.1	Form of Common Stock Certificate	S-1/A	4.1	07/10/2014	
4.2	Form of 2019 Pre-Funded Warrant	8-K	4.1	07/22/2019	
4.3	Form of May 2020 Pre-Funded Warrant	8-K	4.1	05/28/2020	
4.4	Form of December 2020 Pre-Funded Warrant	8-K	4.1	12/09/2020	
4.5	Description of Securities	10-K	4.4	02/27/2020	
10.1*	Amended and Restated 2014 Equity Incentive Plan	10-Q	10.2	08/08/2016	
10.2*	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan	S-1	10.2	06/20/2014	
10.3*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice	10-Q	10.2	11/01/2023	
10.4*	2014 Employee Stock Purchase Plan	S-1/A	10.8	07/10/2014	
10.5*	Atara Biotherapeutics, Inc. Third Amended and Restated 2018 Inducement Plan	S-8	4.3	07/22/2022	
10.6*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the Inducement Plan	10-Q	10.2	11/07/2019	
10.7*	Form of Stock Option Agreement and Stock Option Grant Notice under the Inducement Plan	10-Q	10.3	05/08/2018	
10.8*	Forms of Inducement Grant Notice and Inducement Grant Agreement	10-Q	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	10.9	06/20/2014	
10.10*	Form of Atara Biotherapeutics, Inc. Executive Employment Agreement	10-K	10.39	02/28/2022	
10.11*	Executive Employment Agreement, dated May 23, 2019, by and between Pascal Touchon and Atara Biotherapeutics, Inc.	8-K	10.1	05/28/2019	
10.12†	Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015	S-1	10.30	06/29/2015	
10.13†	Amendment No. 1 to the Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of August 30, 2018	10-K	10.14	02/26/2019	
10.14	Office Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated as of December 9, 2015	10-K	10.29	03/04/2016	
10.15	First Amendment to Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated October 21, 2020	10-Q	10.4	11/09/2020	
10.16	Second Amendment to Lease, by and between Atara Biotherapeutics, Inc. and 611 Gateway Center LP, LLC, dated December 9, 2021	10-K	10.36	02/28/2022	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Filing Date	
10.17	Standard Industrial Lease by and between Thousand Oaks Industrial Portfolio, LLC and Atara Biotherapeutics, Inc. dated February 6, 2017	10-Q	10.1	05/04/2017	
10.18	Lease Agreement between LA Region No. 2, LLC and Atara Biotherapeutics, Inc. dated March 17, 2021	10-Q	10.2	05/04/2021	
10.19	First Amended and Restated Exclusive License Agreement by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated March 22, 2021	10-Q	10.3	05/04/2021	
10.20	Fourth Amended and Restated Research and Development Collaboration Agreement between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated December 17, 2021	10-K	10.37	02/28/2022	
10.21	Fourth Amended and Restated Exclusive License Agreement between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated December 17, 2021	10-K	10.38	02/28/2022	
10.22	Asset Purchase Agreement, dated as of January 26, 2022, by and between Atara Biotherapeutics, Inc., FUJIFILM Diosynth Biotechnologies California, Inc., and certain limited purposes, FUJIFILM Holdings America Corporation	8-K	2.1	04/04/2022	
10.23	Master Services and Supply Agreement dated as of January 26, 2022 by and between Atara Biotherapeutics, Inc., and FUJIFILM Diosynth Biotechnologies California, Inc.	10-Q	10.1	05/05/2022	
10.24+	Purchase and Sale Agreement between Atara Biotherapeutics, Inc., and HCR Molag Fund, L.P., dated December 20, 2022	10-K	10.46	02/08/2023	
10.25	Amendment No. 2 to Commercial Manufacturing Services Agreement dated as of May 31, 2022 by and between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc.	10-Q	10.1	08/08/2022	
10.26+	Amendment No. 3 to Commercial Manufacturing Services Agreement dated as of August 1, 2022 by and between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc.	10-Q	10.1	11/08/2022	
10.27+	Amendment No. 4 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated January 30, 2023	10-Q	10.1	05/08/2023	
10.28+	Amendment No. 5 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated September 27, 2023	10-Q	10.1	11/01/2023	
10.29+	Amendment No. 6 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated December 30, 2023				X
10.30+	Amendment No. 7 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated January 31, 2024				X
10.31+	Amended and Restated Commercialization Agreement by and between Atara Biotherapeutics, Inc. and Pierre Fabre Medicament dated October 31, 2023				X
21.1	List of Subsidiaries				X
23.1	Consent of Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (included on signature page)				

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Filing Date	
31.1	Certification of the Chief Executive Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of the Chief Financial Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
97.1	Incentive Compensation Recoupment Policy				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

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

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

* Indicates management contract or compensatory plan or arrangement.

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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Thousand Oaks, State of California, on the 28th day of March, 2024.

Atara Biotherapeutics, Inc.

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

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

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

Signature	Title	Date
/s/ Pascal Touchon Pascal Touchon	President, Chief Executive Officer and Director (*Principal Executive Officer*)	March 28, 2024
/s/ Eric Hyllengren Eric Hyllengren	Chief Financial Officer (*Duly Authorized Officer and Principle Financial and Accounting Officer*)	March 28, 2024
/s/ Carol G. Gallagher Carol G. Gallagher, Pharm. D.	Director, Chair	March 28, 2024
/s/ Eric L. Dobmeier Eric L. Dobmeier	Director	March 28, 2024
/s/ Matthew K. Fust Matthew K. Fust	Director	March 28, 2024
/s/ William K. Heiden William K. Heiden	Director	March 28, 2024
/s/ Ameet Mallik Ameet Mallik	Director	March 28, 2024
Maria Grazia Roncarolo, M.D.	Director	

Exhibit 10.29

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

EXECUTION VERSION

AMENDMENT NO. 6 TO COMMERCIAL MANUFACTURING SERVICES AGREEMENT

This Amendment No. 6 to the Commercial Manufacturing Services Agreement ("**Sixth Amendment**") is made, entered into and effective as of December 30, 2023 (the "**Sixth Amendment Effective Date**") by and between **ATARA BIOTHERAPEUTICS, INC.**, a Delaware corporation with offices at 2380 Conejo Spectrum Street, Suite 200, Thousand Oaks, CA 91320 ("**Atara**"); and **CHARLES RIVER LABORATORIES, INC.** (successor in interest to **COGNATE BIOSERVICES INC.)**, a Delaware corporation with offices at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118 ("**Manufacturer**"). Each of Atara and Manufacturer are referred to in this Sixth Amendment as a "**Party**" and together, the "**Parties**." All capitalized terms used, but not otherwise defined herein, shall have the same meaning ascribed to them in the Commercial Services Agreement (as defined below).

BACKGROUND

WHEREAS, the Parties have entered into that certain Commercial Manufacturing Services Agreement, effective as of January 1, 2020 (as previously amended by that certain First Amendment, dated as of September 1, 2021; by that certain Second Amendment, dated as of May 26, 2022; and by that certain Third Amendment, dated as of August 1, 2022, and by that certain Fourth Amendment, dated as of January 30, 2023, and by that certain Fifth Amendment, dated as of September 27, 2023, the "**Commercial Services Agreement**"), pursuant to which Atara engaged Manufacturer to perform certain commercial manufacturing services in relation to Atara's products, as further described in individual work orders entered into thereunder;

WHEREAS, the Parties desire to amend the Commercial Services Agreement and certain Work Orders thereto as set forth in this Sixth Amendment; and

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

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

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

> "14.1 **Term.** This Agreement will take effect as of the Effective Date and, unless earlier terminated pursuant to this Article 14, will expire on **January 31, 2024** (the "Final Date" and such period between February 1, 2023 and the Final Date, the "Remaining Period"). Notwithstanding the termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to any active or in progress Work Orders (including Delivery of the final Remaining Batches and any PBMC Batches ordered during the Remaining Period) until each such Work Order has been completed, expired or otherwise terminated in accordance with the terms herein or therein."

2.Exhibit B to that certain Fifth Amendment to Commercial Manufacturing Services Agreement dated as of January 30, 2023 (the "Fifth Amendment") is hereby deleted in its entirety and replaced by Exhibit A to that certain Sixth Amendment.

3.The Commercial Services Agreement is hereby amended by deleting the last sentence of Section 8.9(b)(iii) in its entirety and replacing it as follows:

"The parties agree to negotiate in good faith a new commercial manufacturing agreement by [[***]], and if the parties are unable to finalize such new agreement prior to [[***]], the parties shall mutually agree upon an extension of the Remaining Period, which will include payment of applicable Suite Fees and new Batch commitments to ensure continuity of supply of Product until such new agreement is executed."

4. This Sixth Amendment is governed by and interpreted in accordance with the laws of the State of New York, U.S.A., without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Sixth Amendment. Except as specifically amended by this Sixth Amendment, the terms and conditions of the Commercial Services Agreement shall remain in full force and effect. This Sixth 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 Commercial Services Agreement, as amended by this Sixth Amendment, including all appendices, exhibits and schedules to each of the foregoing, together with all Work Orders executed by the Parties, constitute the entire agreement between the Parties relating to the subject matter of the Commercial Services Agreement and supersede all previous oral and written communications, including all previous agreements, between the Parties.

[SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the undersigned have executed this Sixth Amendment as of the Sixth Amendment Effective Date.

ATARA BIOTHERAPEUTICS, INC.

By: /s/ Cokey Nguyen

Print Name: Cokey Nguyen

Title: EVP, CSO and CTO

CHARLES RIVER LABORATORIES, INC.

By: /s/ Kerstin Dolph

Print Name: Kerstin Dolph

Title: CSVP Global Biologics Testing Solutions

EXHIBIT A

UPDATED PRODUCTION FORECAST STARTS

[[***]]

Exhibit 10.30

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

EXECUTION VERSION

AMENDMENT NO. 7 TO COMMERCIAL MANUFACTURING SERVICES AGREEMENT

This Amendment No. 7 to the Commercial Manufacturing Services Agreement ("**Seventh Amendment**") is made, entered into and effective as of January 31, 2024 (the "**Seventh Amendment Effective Date**") by and between **ATARA BIOTHERAPEUTICS, INC.**, a Delaware corporation with offices at 2380 Conejo Spectrum Street, Suite 200, Thousand Oaks, CA 91320 ("**Atara**"); and **CHARLES RIVER LABORATORIES, INC.** (successor in interest to **COGNATE BIOSERVICES INC.)**, a Delaware corporation with offices at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118 ("**Manufacturer**"). Each of Atara and Manufacturer are referred to in this Seventh Amendment as a "**Party**" and together, the "**Parties**." All capitalized terms used, but not otherwise defined herein, shall have the same meaning ascribed to them in the Commercial Services Agreement (as defined below).

BACKGROUND

WHEREAS, the Parties have entered into that certain Commercial Manufacturing Services Agreement, effective as of January 1, 2020 (as previously amended by that certain First Amendment, dated as of September 1, 2021; by that certain Second Amendment, dated as of May 26, 2022; and by that certain Third Amendment, dated as of August 1, 2022, and by that certain Fourth Amendment, dated as of January 30, 2023, by that certain Fifth Amendment, dated as of September 27, 2023 (the "**Fifth Amendment**"), and by that certain Sixth Amendment, dated as of December 30, 2023 (the "**Sixth Amendment**"), the "**Commercial Services Agreement**"), pursuant to which Atara engaged Manufacturer to perform certain commercial manufacturing services in relation to Atara's products, as further described in individual work orders entered into thereunder;

WHEREAS, the Parties desire to amend the Commercial Services Agreement and certain Work Orders thereto as set forth in this Seventh Amendment; and

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

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

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

> "14.1 **Term.** This Agreement will take effect as of the Effective Date and, unless earlier terminated pursuant to this Article 14, will expire on **March 31, 2024** (the "Final Date" and such period between February 1, 2023 and the Final Date, the "Remaining Period"). Notwithstanding the termination or expiration of this Agreement, the terms and conditions of this Agreement shall continue to apply to any active or in progress Work Orders (including Delivery of the final Remaining Batches and any PBMC Batches ordered during the Remaining Period) until each such Work Order has been completed, expired or otherwise terminated in accordance with the terms herein or therein."

2. Exhibit A to the Sixth Amendment is hereby deleted in its entirety and replaced by Exhibit A to this Seventh Amendment.

3. Exhibit A to the Fifth Amendment is hereby deleted in its entirety and replaced by Exhibit B to this Seventh Amendment.

4.The Commercial Services Agreement is hereby amended by deleting the last sentence of Section 8.9(b)(iii) in its entirety and replacing it as follows:

> "The parties agree to negotiate in good faith a new commercial manufacturing agreement by [[***]] and if the parties are unable to finalize such new agreement prior to [[***]], the parties shall mutually agree upon an extension of the Remaining Period, which will include payment of applicable Suite Fees and new Batch commitments to ensure continuity of supply of Product until such new agreement is executed."

5.This Seventh Amendment is governed by and interpreted in accordance with the laws of the State of New York, U.S.A., without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Seventh Amendment. Except as specifically amended by this Seventh Amendment, the terms and conditions of the Commercial Services Agreement shall remain in full force and effect. This Seventh 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 Commercial Services Agreement, as amended by this Seventh Amendment, including all appendices, exhibits and schedules to each of the foregoing, together with all Work Orders executed by the Parties, constitute the entire agreement between the Parties relating to the subject matter of the Commercial Services Agreement and supersede all previous oral and written communications, including all previous agreements, between the Parties.

[SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the undersigned have executed this Seventh Amendment as of the Seventh Amendment Effective Date.

ATARA BIOTHERAPEUTICS, INC.

By: /s/ Pascal Touchon

Print Name: Pascal Touchon

Title: CEO

CHARLES RIVER LABORATORIES, INC.

By: /s/ Kerstin Dolph

Print Name: Kerstin Dolph

Title: Sr. Corporate Vice President | Global Manufacturing

EXHIBIT A

UPDATED PRODUCTION FORECAST STARTS

[[***]]

EXHIBIT B

SUITE FEES

[[***]]

Exhibit 10.31
EXECUTION VERSION

Between:

Atara Biotherapeutics, Inc.

And:

Pierre Fabre Medicament

AMENDED AND RESTATED COMMERCIALIZATION AGREEMENT

Dated October 31, 2023

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AMENDED AND RESTATED COMMERCIALIZATION AGREEMENT

This Amended and Restated Commercialization Agreement (this "**Agreement**") is made as of October 31, 2023 (the "**Execution Date**"), by and between Atara Biotherapeutics, Inc., incorporated under the laws of Delaware and having its registered office at 2380 Conejo Spectrum Street, Suite 200, Thousand Oaks, CA 91320 ("**Atara**"), and Pierre Fabre Medicament, having its registered office at les Cauquillous, 81500 Lavaur, France ("**Partner**"). Atara and Partner are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, Atara is engaged in the development and manufacture of T-cell immunotherapies;

WHEREAS, Atara is conducting pivotal clinical studies with the Product (as defined below);

WHEREAS, Atara has obtained marketing approvals for the Product in the Primary Indication in the EU and UK, and has transferred these marketing approvals to Partner;

WHEREAS, Partner has expertise in commercializing biological and pharmaceutical products for the treatment of oncologic diseases in the Territory (as defined herein);

WHEREAS, the Parties previously entered into that certain Commercialization Agreement (the "**Original Commercialization Agreement**") dated October 2, 2021 (the "**Original Effective Date**"), as amended on September 27, 2022, pursuant to which Atara granted Partner certain exclusive rights relating to the Commercialization (as defined herein) of the Product in the Initial Territory (as defined herein), and those certain Original Ancillary Agreements (as defined herein); and

WHEREAS, the Parties now desire to continue and expand their relationship such that Partner will Commercialize the Product in the Field (each, as defined herein) in the Initial Territory and the Additional Territory (as defined herein) pursuant to the terms and conditions of this Agreement and certain newly amended and restated Ancillary Agreements (as defined herein).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, Atara and Partner hereby agree as follows:

ARTICLE 1
Definitions

The terms in this Agreement with initial letters capitalized shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 "**Accounting Standards**" shall mean, with respect to Atara, GAAP, and with respect to Partner, IFRS.

1.2 "**Additional Indication**" means an indication in the Field other than the Primary Indication, including, but not limited to, a Multi-Cohort Indication.

1.3 "**Additional Territory**" means all countries of the world excluding the Initial Territory.

1.4 "**Additional Upfront Payment**" has the meaning given in Section 10.1, hereto.

1.5 "**Adverse Event**," "**Serious Adverse Event**" and "**Serious Adverse Drug Reaction**" shall have the meanings provided to such terms in the ICH guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

1.6 "**Affiliate**" means, with respect to a Party, any Entity that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" means direct or indirect ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the Entity controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity.

1.7 "**Alliance Manager**" has the meaning given in Section 3.6, hereto.

1.8 "**Ancillary Agreements**" means, collectively, the Manufacturing and Supply Agreement, the Pharmacovigilance Agreement, and the Quality Agreement, in each case, newly amended and restated.

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

1.10 "**Antitrust Conditions**" has the meaning given in Section 16.1(b), hereto.

1.11 "**Approved Sublicensee**" has the meaning given in Section 2.2(a), hereto.

1.12 "**APAC Region**" means the following territories: mainland China, the Hong Kong Special Administrative Region, Japan, the Macau Special Administrative Region, Australia, New Zealand, Taiwan, Singapore, Indonesia, Malaysia, Philippines, Thailand, India, Vietnam, and South Korea.

1.13 "**Assignment Date**" means, with respect to each Transferred Contract, (a) the applicable assignment date set forth in Schedule 1.199, (b) if later than the date pursuant to clause (a), then the date upon which the applicable Transferred Contract is bifurcated and assigned in accordance with Section 4.3, or (c) such other date as may be mutually agreed upon by the Parties in writing.

1.14 "**Atara 205 Study**" means the multicenter, multicohort, open-label, single-arm, Phase 2 Clinical Study having the ClinicalTrials.gov identifier NCT04554914, as designed as of the Execution Date.

1.15 "**Atara 302 Study**" means the multicenter, open-label, Phase 3 Clinical Study having the ClinicalTrials.gov identifier NCT03394365, as designed as of the Execution Date.

1.16 "**Atara 902 EAP Observational Study**" means the ongoing Observational Study describing the analysis of data collected as part of the Atara EU EAP/SPU Program, as designed as of the Execution Date.

1.17 "**Atara EU EAP/SPU Program**" means Atara's Early Access Program that provided Product for named-patient use in the Initial Territory and that the regulatory responsibility of which has been transitioned from Atara to Partner as of the Execution Date.

1.18 "**Atara Indemnified Person**" has the meaning given in Section 12.2, hereto.

1.19 "**Atara Intellectual Property**" means (a) Atara Patent Rights, and (b) Know-How that is (i) Controlled by Atara as of the Execution Date or during the Term, and (ii) necessary or reasonably useful to research, Develop, make, have made, use, sell, offer for sale and import the Product and any related companion diagnostics and to conduct Cell Selection in the Field in the Territory. Atara Intellectual Property shall also include [***].

1.20 "**Atara Manufacturing Facility**" means one or more facilities of (a) [***], or (h) any other facility of an Atara Affiliate or Third Party subcontractor subject to Partner's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

1.21 "**Atara Officers**" means the officers listed in Exhibit G.

1.22 "**Atara Patent Rights**" means (a) the Patent Rights listed on Exhibit C and/or (b) any Patent Rights Controlled by Atara as of the Execution Date or during the Term of the Agreement that, but for the licenses granted under this Agreement, would be infringed by the research, Development, making, having made, using, selling, offering for sale and importing the Product and any related companion diagnostics in the Field in the Territory; and (c) all additions, divisions, continuations, substitutions, re-issues, re-examinations, registrations, patent term extensions, supplemental protection certificates, and renewals of any of the foregoing Patent Rights covered in subsections (a) and (b).

1.23 "**Atara's knowledge**" means the knowledge of the Atara Officers after having conducted reasonable internal inquiries on matters that a reasonably prudent person in a comparable position to each of such Atara Officers would be aware of having made reasonable inquiries.

1.24 "**Bifurcated Contract**" has the meaning given in Section 4.3(b), hereto.

1.25 "**BLA**" means a Biologics License Application, including all supplements and amendments thereto, filed with the FDA in the United States with respect to a Product, as defined in Title 21 of the U.S. Code of Federal Regulations, Section 601.2 et seq.

1.26 "**BLCL**" means B-lymphoblastoid cell lines.

1.27 "**Business Day**" means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by law to be closed in the State of New York, United States or Paris, France.

1.28 "**Calendar Quarter**" means each three (3) month period commencing January 1, April 1, July 1 or October 1 of any year; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.29 "**Calendar Year**" means the period beginning on the 1st of January and ending on the 31st of December of the same year; provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.30 "**Cell Selection**" means the process, solely with respect to the Product, of (a) receiving (from the Partner, as applicable) the necessary high-resolution HLA profile information for any patient, (b) based on said patient's HLA profile, identifying a cell line from available inventory of Product held by Partner that is suitable for administration to said patient, and (c) communicating the identity of the recommended cell line to Partner, as applicable, as such process may (i) be amended or modified by Atara from time to time during the R&D Pre-Transfer Period, provided that any such amendment or modification may not be implemented with respect to Commercialization of the Product in the Territory without Partner's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed.

1.31 "**Cell Therapy Restricted Product**" has the meaning given in Section 7.12, hereto.

1.32 "**Change of Control**" means (a) a merger or consolidation of a Party with a Third Party that results in the voting securities of a Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of a Party, or (c) the sale or other transfer to a Third Party of all or substantially all of a Party's and its Affiliates' assets.

1.33 "**Claim**" means a Third Party demand, claim, action, proceeding, order, finding or verdict (whether criminal or civil, in contract, tort or otherwise) seeking or awarding losses, damages, legal costs, other expenses of any nature, or equitable remedies of any nature, including restitution and injunctive relief.

1.34 "**Clinical Study**" means any interventional human clinical study of the Product and specifically excludes any Observational Study.

1.35 "**Closing Notice**" has the meaning given in Section 16.2(a), hereto.

1.36 "**CMC**" means chemistry, manufacturing and controls.

1.37 "**Combination Product**" means a product comprising both (a) the Product, and (b) one (1) or more Other Component(s).

1.38 "**Commercial Sale**" means an invoiceable sale by Partner, its Affiliate, or Approved Sublicensee to a Third Party, excluding any sales under an Early Access Program.

1.39 "**Commercialize**" and "**Commercialization**" are used interchangeably to mean any and all activities directed to the use, sale, offer for sale and import of the Product, and inclusive of Pre-Launch, launch, promotion, marketing, pricing, reimbursement, sale, and distribution of the Product, including: (a) strategic marketing, sales force detailing, advertising, and market and Product support; (b) all customer support, Product distribution, invoicing and sales activities, (c) market access activities (pricing, Pricing Approval, and reimbursement) and (d) medical activities with respect to the Product in the Territory in support of the sales, promotion, marketing or use of the Product in the Territory. For the avoidance of doubt, "Commercialize" and "Commercialization" shall include any activities directed or relating to Early Access Programs, and Observational Studies (other than the Atara 902 EAP Observational Study), and exclude any activities directed or relating to Development, Cell Selection or Manufacturing.

1.40 "**Commercially Reasonable Efforts**" means, with respect to particular obligations or tasks, such level of efforts and resources applied to carry out such obligations or tasks in a sustained manner consistent with the efforts and resources commonly used in the biopharmaceutical industry by a company of comparable size in connection with the development, manufacture or commercialization of products, as the case may be, to accomplish such obligations or tasks, at the same stage of development or commercialization, as applicable, for internally developed healthcare products in a similar area with similar market potential, at a similar stage of their product life taking into account, [***]. "Commercially Reasonable Efforts" shall require each Party, with respect to the activities which it has to perform using Commercially Reasonable Efforts, at a minimum to the extent commercially reasonable: (a) to reasonably promptly assign responsibility for its obligations hereunder to qualified employees, set reasonable objectives for carrying out such obligations, and monitor and hold employees accountable for their activities with respect to such objectives; and (b) to make and implement decisions, including allocating resources that are reasonably required to implement decisions, to diligently advance progress with respect to such objectives.

1.41 "**Competitive Infringement**" has the meaning given in Section 9.3(a), hereto.

1.42 "**Competitive Infringement Action**" has the meaning given in Section 9.3(b), hereto.

1.43 "**Confidential Information**" means all proprietary Know-How, unpublished patent applications and other information and data of a financial, commercial, business, operational or technical nature that: (a) the Disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or any of its Affiliates in connection with this Agreement, whether prior to or during the Term and whether made available orally, by observation, in writing or in electronic form; or (b) the Receiving Party has learned from the disclosing Party in the course of this Agreement, in each case including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement.

1.44 "**Control**" or "**Controlled**" means with respect to any material, Know-How or other information or intellectual property right, the possession (whether by license, other than solely by virtue of licenses granted in this Agreement, or ownership) by a Party or its Affiliates of the ability to grant to the other Party access, a license, or a sub-license or other right thereunder without breaching or violating the terms of any applicable agreement or other arrangement with a Third Party.

1.45 "**Cover**" means with respect to any Patent Right and activity, that such Patent Right would be infringed by such activity in the absence of the licenses granted pursuant to this Agreement.

1.46 "**CRL**" has the meaning given in Section 8.5(c), hereto.

1.47 "**CTA**" shall mean (a) a clinical trial application (including any amendments thereto) as provided for in European Community Directive 2001/20/EC and/or European Union Regulation 536/2014 and the regulations promulgated thereunder, as applicable, filed with a Regulatory Authority in the European Union before the commencement of Clinical Studies for a Product, or any comparable filing with any Regulatory Authority in any other jurisdiction in the Territory (including any Investigational New Drug Application filed with a Regulatory Authority in the United States pursuant to 21 C.F.R. §312); or (b) documentation issued by a Regulatory Authority that permits the conduct of Clinical Studies for a Product in any jurisdiction in the Territory.

1.48 "**Current Studies**" means the Atara 205 Study, the Atara 302 Study, and the Atara 902 EAP Observational Study.

1.49 "**Data Protection Laws**" means all applicable Laws, including the Health Insurance Portability and Accountability Act, the California Consumer Privacy Act of 2018, and the General Data Protection Regulation 2016/679, and any national other legislation relating to privacy and data protection, direct marketing or the interception or communication of electronic messages, in each case as amended, consolidated, re-enacted or replaced from time to time.

1.50 "**Data Subject**" means a natural person who is an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

1.51 "**Develop**" or "**Development**" means any and all activities related to research, non-clinical, pre-clinical and Clinical Studies with respect to the Product, including, without limitation, supporting any Investigator Sponsored Clinical Trials, but excluding Manufacturing of the Product for the purpose of conducting the foregoing activities

1.52 "**Development Data**" shall have the meaning given in Section 5.4(a). Development Data includes, but is not limited to, Regulatory Data.

1.53 "**Dispute**" shall have the meaning given in Section 16.12(a).

1.54 "**Distributors**" shall have the meaning given in Section 2.2(b).

1.55 "**DMF**" means a drug master file and all equivalents in any country or jurisdiction for the Product, and any components of such Product, submitted by a Party, its Affiliates and/or a sublicensee, to Regulatory Authorities.

1.56 "**DOJ**" has the meaning given in Section 16.1(a), hereto.

1.57 "**Dollar**" or "**$**" means the legal tender of the United States.

1.58 "**Early Access Approvals**" means the permissions, exemptions, approvals, authorizations and/or waivers required by Regulatory Authorities for medical treatments pursuant to an Early Access Program, where the use of such Product is not intended to obtain information about the safety or effectiveness of the Product.

1.59 "**Early Access Program**" or "**EAP**" means the activities directed to (a) supporting a physician's request(s) for the Product for named-patient use, compassionate use, expanded access and hospital exemption in the Territory through an Early Access Approval, (b) the securing of Early Access Approvals for Product, for the use of such treatments, and (c) the labeling, packaging, distribution and sale (as appropriate) of such treatments pursuant to such Early Access Approvals.

1.60 "**EBV Restricted Product**" has the meaning given in Section 7.12, hereto.

1.61 "**EBV+ PTLD**" means EBV-positive post-transplant lymphoproliferative disease.

1.62 "**EC**" means the European Commission, or any successor entity thereto performing similar functions.

1.63 "**Effective Date**" has the meaning given in Section 16.2(b), hereto.

1.64 "**EMA**" means the European Medicines Agency, or any successor entity thereto performing similar functions.

1.65 "**Entity**" means a partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization.

1.66 "**Epstein Barr Virus**" or "**EBV**" means human herpesvirus 4.

1.67 "**Europe**" means (a) the twenty-seven (27) countries of the European Union as constituted on the Original Effective Date, and (b) Iceland, Liechtenstein, and Norway.

1.68 "**Excess Costs**" has the meaning given in Section 10.11(d)(ii), hereto.

1.69 "**Executive Officers**" has the meaning given in Section 3.8(b), hereto.

1.70 "**Existing Agreements**" means (a) the MSK Agreement and (b) each of the Material Contracts (in each case, with respect to (a) and (b), solely to the extent the terms contained therein are relevant to the Product), provided that, with respect to clause (b), each such contract shall only constitute an Existing Agreement until the earlier of (i) the assignment and transfer thereof to Partner, (ii) the bifurcation thereof and the assignment and transfer of such bifurcated contract to Partner, (iii) the expiration of the Transition Services Agreement, or (iv) Partner's execution of a separate agreement with any Third Party(ies) for comparable goods or services as those provided to Atara under such contract, in each case, with respect to (i) through (iv), in accordance with Section 4.3.

1.71 "**FDA**" means the U.S. Food and Drug Administration, and any successor agency thereto.

1.72 "**FDBC**" has the meaning given in Section 8.2, hereto.

1.73 "**Field**" means all human therapeutic and diagnostic uses, except multiple sclerosis and other autoimmune conditions.

1.74 "**Financial Report**" has the meaning given in Section 10.11(b), hereto.

1.75 "**First Commercial Sale**" means, with respect to any country in the Territory the first Commercial Sale in the Field by or on behalf of Partner, its Affiliate or its Approved Sublicensee to a Third Party (including to a Distributor) in such country. Notwithstanding the foregoing, any *bona fide* invoiced sales of Product for a commercial margin in a country in the Territory by Partner, its Affiliate or its Approved Sublicensee following receipt of Regulatory Approval, but prior to obtaining Pricing Approval (e.g., sales of Product at a commercial margin under the Temporary Authorization for Use Program in France), shall be deemed a "First Commercial Sale" of the Product in such country.

1.76 "**First Inventory Purchase**" has the meaning given in Section 8.6(a), hereto.

1.77 "**FTC**" has the meaning given in Section 16.1(a), hereto.

1.78 "**FTE**" means the equivalent of the work of one (1) full-time employee of Atara or its Affiliates for one (1) year consisting of 1800 hours per year [***].

1.79 "**FTE Costs**" means the product of: (a) that number of FTEs (including partial FTEs, as applicable) used by Atara or its Affiliates in directly performing activities assigned to Atara under and in accordance with the Transition Plan, multiplied by (b) the applicable FTE Rate.

1.80 "**FTE Rate**" shall mean the rates for the engagement of FTEs, as set forth on Exhibit H, [***].

1.81 "**GAAP**" means the generally accepted accounting principles in the United States as generally and consistently applied by Atara.

1.82 "**Generic Competitor**" means, with respect to a Product, on a country-by-country basis within the Territory, one or more pharmaceutical product(s) (a) sold under a Marketing Authorization granted by an applicable Regulatory Authority to a Third Party (who is not an Affiliate of Partner or an Approved Sublicensee or a Distributor), (b) that contains the same or biologically similar active ingredient as the Product (whether or not in the same formulation or a similar formulation as the Product), and (c) is approved in reliance of a prior Marketing Authorization of the Product granted by the applicable Regulatory Authority, including for the avoidance of doubt, the Marketing Authorization transferred by Atara to Partner under this Agreement.

1.83 "**Generic Market Share**" means, with respect to a Product in a country, the total unit volume of Generic Competitor(s) of such Product sold in such country, as a percentage of the combined unit volume of such Product and such Generic Competitor(s), in the aggregate in such country, for the current Calendar Quarter (i.e., the Calendar Quarter for which royalties are being calculated under Section 10.4) and the preceding Calendar Quarter. Such unit volumes shall be determined by the number of unit sales given for such Product and such Generic Competitor(s) in aggregate, during such period (as evidenced by data from IMS Health or other data service reasonably acceptable to both Parties).

1.84 "**Global Safety Database**" means the database containing worldwide safety data including Adverse Events, Serious Adverse Events, adverse reactions, Serious Adverse Drug Reactions, safety reports related to special situations for the Product as defined in the applicable Laws, and pregnancy reports for the Product.

1.85 "**Good Clinical Practices**" or "**GCP**" means all applicable current good clinical practices, including, as applicable, (a) the standards detailed in the ICH Harmonized Tripartite Guideline for Good Clinical Practice and (b) similar standards, guidelines and regulations promulgated or otherwise required by other applicable Regulatory Authorities, in each case, as they may be amended from time to time.

1.86 "**Good Laboratory Practices**" or "**GLP**" means all applicable current good laboratory practices, including, as applicable, (a) the standards detailed in Directive 2004/10/EC and (b) similar standards, guidelines and regulations promulgated or otherwise required by other applicable Regulatory Authorities, in each case, as they may be amended from time to time.

1.87 "**Good Manufacturing Practices**" or "**GMP**" means all applicable current good manufacturing practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Articles 210, 211, 601 and 610, (b) the principles detailed in the ICH Q7 guidelines, and (c) the equivalent applicable Law in any relevant country, each as may be amended and applicable from time to time.

1.88 "**Government Authority**" means any federal, state, national, regional, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.89 "**HLA**" means human leukocyte antigen.

1.90 "**HSR**" has the meaning given in Section 16.1(a), hereto.

1.91 "**HSR Clearance Date**" has the meaning given in Section 16.1(b), hereto.

1.92 "**ICH**" means International Conference on Harmonization.

1.93 "**IFRS**" means the International Financial Reporting Standards generally and consistently applied by Partner.

1.94 "**IND**" means an Investigational New Drug application for submission to the FDA or any equivalent counterpart application in any country other than the United States, including all supplements and amendments thereto.

1.95 "**Indemnitee**" has the meaning given in Section 12.3, hereto.

1.96 "**Indemnitor**" has the meaning given in Section 12.3, hereto

1.97 "**Initial Territory**" means:

(a) Europe, the United Kingdom and Switzerland (collectively, the "**European Region**");

(b) Eastern Europe and Asian countries (specifically and limited to, Albania, Serbia, Bosnia-Herzegovina, Kosovo, Republic of Macedonia, Montenegro, Turkey, Russia, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Tajikistan, Uzbekistan, Republic of Moldova, Turkmenistan, Ukraine, and Georgia) (collectively, the "**Eastern Europe Region**");

(c) African countries (specifically and limited to, Tunisia, Morocco, Algeria, South Africa, Burundi, Republic of the Congo (Brazzaville), Benin, Burkina Faso, Cameroon, Chad, Democratic Republic of the Congo, Ivory Coast, Gabon, Guinea, Libya, Madagascar, Mali, Mauritania, Mauritius, Niger, Senegal, Togo, Djibouti, and Central African Republic) (collectively, the "**Africa Region**"); and

(d) Middle East countries (specifically and limited to, Egypt, Iran, Iraq, Saudi Arabia, Yemen, Syria, Jordan, United Arab Emirates, Lebanon, Oman, Kuwait, Qatar, Bahrain).

1.98 "**Initial Transition Plan**" has the meaning given in Section 4.1(b), hereto.

1.99 "**Initial Upfront Payment**" has the meaning given in Section 10.1, hereto.

1.100 "**Insolvency Event**" means, in relation to either Party, any one of the following: (a) that Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) that Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings which are dismissed within sixty (60) days); (c) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed in respect of that Party by a court of competent jurisdiction; (d) a notice shall have been issued by a competent authority to convene a meeting for the purpose of passing a resolution to wind up that Party, or such a resolution shall have been passed other than a resolution for the solvent reconstruction or reorganization of that Party; and with respect to Atara only; (e) a resolution shall have been passed by that Party or that Party's directors to make an application for an administration order or to appoint an administrator; or (f) that Party proposes or makes any general assignment, composition or arrangement with or for the benefit of all or some of that Party's creditors or makes or suspends or threatens to suspend making payments to all or some of that Party's creditors.

1.101 "**Interim Covenants**" has the meaning given in Section 16.1(b), hereto.

1.102 "**Investigator Sponsored Clinical Trial**" shall mean a clinical study of a Product that is sponsored and conducted by a physician, physician group or other Third Party not acting on behalf of a Party or an Affiliate, pursuant to a CTA held by such Third Party, and with respect to which a Party or its Affiliate, provides funding or other support for such clinical study.

1.103 "**Joint Steering Committee**" or "**JSC**" has the meaning given in Section 3.1, hereto.

1.104 "**JSC Termination Date**" means the later of (i) the date of expiration of the R&D Pre-Transfer Period or (ii) the Manufacturing Transition Date.

1.105 "**Know-How**" means any and all tangible and intangible information and materials, including research and Development Data, regulatory submissions and correspondence, manufacturing information and processes, formulations, assays, cell lines, sequences, composition of matter, constructs, discoveries, improvements, modifications, processes, methods, protocols, formulas, utility, data (including physical, chemical, biological, toxicological, pharmacological, preclinical, and clinical data), results, inventions, know-how and trade secrets, patentable or otherwise, and all other scientific, marketing, financial and commercial information or data, but excluding any of the foregoing to the extent described or claimed in any Patent Rights.

1.106 "**Label**" or "**Labeling**" refers to such labels and other written, printed or graphic matter, (a) upon any container or wrapper utilized with the Product, or (b) accompanying the Product, including, without limitation, Package inserts and patient-specific information sheet.

1.107 "**LatAm Region**" means the following countries: Mexico, Guatemala, Honduras, El Salvador, Nicaragua, Costa Rica, Belize, Panama, Colombia, Venezuela, Ecuador, Peru, Bolivia, Chile, Guyana, Suriname, Paraguay, Argentina, Uruguay, Brazil, Cuba, the Dominican Republic, Haiti and West Indies.

1.108 "**Law**" means any federal, state, local, foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order by any Government Authority (including, without limitation, any Regulatory Authority), or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law, including, without limitation, applicable Anti-Corruption Laws and GMP, GLP, and GCP standards.

1.109 "**Liens**" has the meaning set forth in Section 11.5(a), hereto.

1.110 "**Licensed Back Data**" means any Development Data assigned by Atara to Partner as well as those generated by or on behalf of Atara in connection with the performance of the activities assigned to Atara under the Transition Plan.

1.111 "**Limited Period**" has the meaning set forth in Section 7.12, hereto.

1.112 "**Major Markets**" means [***].

1.113 "**Manufacture**" or "**Manufacturing**" are used interchangeably herein to mean the operations required, as applicable, to (a) manufacture test, store, and ship Product for any authorized research or Development and for use pursuant to any Early Access Program in the Territory, or (b) manufacture, test, store and ship the Product for any authorized Commercialization in the Territory.

1.114 "**Manufacturing and Supply Agreement**" or "**MSA**" has the meaning given in Section 8.1, hereto.

1.115 "**Manufacturing Transition Date**" has the meaning given in Section 8.5(a) hereto.

1.116 "**Manufacturing Working Group**" or "**MWG**" has the meaning given in Section 3.3(b), hereto.

1.117 "**Material Contracts**" means the contracts entered into by Atara or its Affiliates that are material to the Development, Cell Selection, Manufacture, Regulatory Interactions or Commercialization, as applicable, of the Products, including those listed in Schedule 1.199 as of the Execution Date, as may be updated by Atara from time to time prior to the Manufacturing Transition Date with Partner's prior written consent, not to be unreasonably withheld, conditioned or delayed.

1.118 "**Marketing Authorization**" or "**MA**" means an approval by a Regulatory Authority for the placing in the market of therapeutic products in a country, region or other jurisdiction in the Territory, including, without limitation, a marketing authorization as granted by the EC or the FDA and all amendments and supplements thereto. For the avoidance of doubt, Marketing Authorization does not include Pricing Approvals in any country, region, or jurisdiction in the Territory.

1.119 "**Marketing Authorization Application**" or "**MAA**" means an application for Marketing Authorization and all amendments and supplements thereto prior to its approval,

including all necessary documents, data and other information, including, without limitation any BLA or any application for Marketing Authorization filed with the EMA.

1.120 "**MHRA**" means the Medicines and Healthcare Products Regulatory Agency, or any successor entity thereto performing similar functions.

1.121 "**Middle East Region**" means Middle East countries (specifically and limited to, Egypt, Iran, Iraq, Saudi Arabia, Yemen, Syria, Jordan, United Arab Emirates, Lebanon, Oman, Kuwait, Qatar, Bahrain) and Israel.

1.122 "**MSK**" means the Memorial Sloan Kettering Cancer Center.

1.123 "**MSK Agreement**" means Atara's exclusive license agreement with MSK as Amended and Restated on March 22, 2021, as it may be further amended from time to time and subject to the terms and conditions of this Agreement.

1.124 "**Multi-Cohort Indications**" means any or all indications selected from EBV+ acquired immunodeficiency lymphoproliferative diseases (AID-LPD), EBV+ primary immunodeficiency lymphoproliferative disease (PID-LPD), EBV+ sarcoma, including leiomyosarcomas (LMS), EBV-associated hemophagocytic lymphohistiocytosis (HLH), EBV+ PTLD ineligible for current first line standard of care (rituximab ± chemotherapy) treatment, and EBV+ PTLD with central nervous system involvement.

1.125 "**Net Sales**" means the gross amount billed or invoiced on sales of the Product sold by Partner, its Affiliates or their Approved Sublicensees (including sales of Product by Partner, its Affiliates or their Approved Sublicensees to Distributors, but not by Distributors) to a Third Party in the Territory (other than sales among Partner, its Affiliates and Approved Sublicensees for subsequent resale in which case the first sale to a Third Party that is not an Affiliate or an Approved Sublicensee shall be used for calculation of Net Sales), less the following: [***].

Gross sales of Product shall be deemed to have been made on the date on which they are recognized in Partner's financial accounts, in accordance with their standard accounting procedures. For clarity, Net Sales shall include [***].

Net Sales shall be determined in accordance with Accounting Standards.

In the event that a Product is sold in the form of a Combination Product, then, for the purpose of calculating royalties due, Net Sales will be adjusted by multiplying by the fraction A/(A+B) where A is the gross per unit invoice price of the Product, if sold separately, and B is the gross per unit invoice price of any Other Component(s), if sold separately.

If, on a country-by-country basis, the Other Component(s) are not sold separately in that country, Net Sales will be adjusted by multiplying by the fraction A/C where A is the gross per unit invoice price of the Product, if sold separately, and C is the gross per unit invoice price of the Combination Product. In each case, the gross per unit invoice price shall be those applicable during the relevant Quarter or, if sales of both the Product and the Other Component did not occur in such Quarter, then in the most recent Quarter in which sales of both occurred. If, on a country-by-country basis,

neither the Product nor the Other Component are sold separately in such country, then the fraction by which the Net Sales value shall be multiplied shall be determined between the Parties in good faith.

1.126 "**New Manufacturing Process Transition Period**" has the meaning given in Section 3.9(b), hereto.

1.127 "**Nordic Countries**" means Denmark, Finland, Norway and Sweden.

1.128 "**North America Region**" means the United States of America, the Commonwealth of Puerto Rico, Canada, Guam, Saipan, St. Thomas, St. Croix, St. Maarten, St. Lucia, St. Vincent, Tortola, Anguilla and Grenada

1.129 "**Notice Review Period**" has the meaning given in Section 16.2(a), hereto.

1.130 "**Objection Notice**" has the meaning given in Section 16.2(a), hereto.

1.131 "**Observational Study**" means any non-interventional study for the Product. Observational Studies may include patient registries, surveillance studies, health economic studies or similar activities.

1.132 "**Original Ancillary Agreements**" means, collectively, that certain Manufacturing and Supply Agreement dated December 21, 2022 between the Parties (the "**Original Manufacturing and Supply Agreement**"); that certain Pharmacovigilance Agreement dated October 5, 2022 between the Parties (the "**Original Pharmacovigilance Agreement**"); and that certain Quality Agreement dated December 21, 2022 between the Parties (the "**Original Quality Agreement**").

1.133 "**Original Commercialization Agreement**" has the meaning given in the recitals, hereto.

1.134 "**Original Effective Date**" has the meaning given in the recitals, hereto.

1.135 "**Orphan Drug Designation**" means orphan designation (EU/3/16/1627) granted by the EC for the Product in relation to the Primary Indication, the orphan designation granted by the FDA on February 4, 2016 for the Product in relation to the Primary Indication, and any other orphan designation (i) granted by the EC for the Product with respect to an Additional Indication(s) or (ii) granted by any Regulatory Authority within a country or regulatory region within the Territory with respect to the Product.

1.136 "**Other Component**" means a product, component, or medical device as a companion to the Product, or co-packaged, or co-distributed with the Product.

1.137 "**Out-of-Pocket Costs**" means amounts paid to Third Party vendors, consultants, suppliers or contractors, for services or materials provided by them directly in the performance of activities under the Transition Plan, to the extent such services or materials apply directly to the Product. [***].

1.138 "**Package**," "**Packaged**" or "**Packaging**" means all primary and/or secondary containers, including cartons, shipping cases, printed materials, or any other like matter used in packaging or accompanying a Product for Commercial Sale.

1.139 "**Partner Indemnified Person**" has the meaning given in Section 12.1, hereto.

1.140 "**Partner Intellectual Property**" has the meaning given in Section 5.4(b), hereto.

1.141 "**Patent Rights**" means any and all issued patents and patent applications existing upon the Original Effective Date and in the future, including, without limitation, provisional applications, continuation applications, substitutions, continuations-in-part, divisional applications, renewals, Patent Cooperation Treaty applications, and all letters patent granted thereon, invention patents, utility model patents, industrial design patents, all patents-of-addition, reexaminations, reissues, registrations, confirmations, revalidations, certificates of addition, utility models and petty patents, including extensions or restorations of terms thereof by existing or future extension or restoration mechanisms (including regulatory extensions), pediatric use extensions, supplementary protection certificates or any other such right, together with any foreign counterparts thereof.

1.142 "**PBMC**" means Peripheral Blood Mononuclear Cells.

1.143 "**Person**" means any individual, Entity or Government Authority.

1.144 "**Pharmacovigilance Agreement**" shall have the meaning given in Section 6.3.

1.145 "**Pre-Launch**" means all activities undertaken prior to and in preparation for the launch of the Product in the Field in the Territory. Pre-Launch shall include market research, key opinion leader development, advisory boards, medical education, patient associations, disease-related public relations, health care economic studies, sales force training and other pre-launch activities prior to the First Commercial Sale of the Product in a given country, region, or other jurisdiction in the Territory.

1.146 "**Pricing Approval**" means the approval, agreement, determination or decision from a Government Authority establishing the price and/or reimbursement status for the Product for sale in a given country, region or jurisdiction in the Territory, as required by applicable Law in such country or other regulatory jurisdiction prior to the sale of the Product in such country, region or jurisdiction in the Territory.

1.147 "**Primary Indication**" means (as may be amended from time to time in accordance with the terms of this Agreement) EBV+ PTLD in patients who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy, unless chemotherapy is considered inappropriate.

1.148 "**Product**" means tabelecleucel, an allogeneic T-cell immunotherapy selective for the tumor-associated antigens expressed by EBV. Product includes, without limitation, a Product sold in the form of a Combination Product.

1.149 "**Product Material Adverse Effect**" means a material adverse effect on [***].

1.150 "**Product Patent Rights**" means the Patent Rights listed in sections (B) and (C) of Exhibit C, attached hereto.

1.151 "**Product-Specific Intermediates**" means PBMCs and BLCLs.

1.152 "**Product Supply Price**" [***].

1.153 "**Product Trade Dress**" means trade dress for use in connection with the Commercialization of the Product in the Field in the Territory.

1.154 "**Product Trademarks**" means (1) (a) the "tab-cel®" trademarks owned or Controlled by Atara and designated by Atara for use with the Product in the Territory, (b) the "Ebvallo®" trademarks owned or Controlled by Atara and designated by Atara for use with the Product in the Territory, and (c) any other trademark owned or Controlled by Atara for use in connection with the Commercialization of a Product in the Field the Territory, each, as listed in Exhibit E, together with all goodwill associated therewith or arising therefrom, or (2) any other trademark specifically used by Partner in connection with the Commercialization of the Product in the Field in the Territory.

1.155 "**Promotional Materials**" means all written, printed, video, digital, or graphic advertising, promotional, educational and communication materials (other than the Product Labels and Package inserts) for marketing, advertising, promoting or otherwise Commercializing the Product.

1.156 "**Public Official or Entity**" shall mean (a) an individual or entity operating in an official or public capacity on behalf of a Government Authority (including physicians, hospital administrators, and other healthcare professionals working for or on behalf of state-controlled healthcare organization), (b) any official or employee of a quasi-public or non-governmental international organization, (c) any employee or other person acting for or on behalf of any entity that is wholly or partially government owned or controlled by a Government Authority, (d) any person exercising legislative, administrative, judicial, executive, or regulatory functions for or pertaining to a Government Authority (including any independent regulator), (e) any political party official, officer, employee, or other person acting for or on behalf of a political party and (f) any candidate for public office.

1.157 "**Publishing Party**" shall have the meaning given in Section 13.9(a), hereto.

1.158 "**PV2.0**" means [***].

1.159 "**PV3.0**" means [***].

1.160 "**PV3.2AB**" means [***].

1.161 "**PV3.2AT**" means [***].

1.162 "**PV3.3**" means [***].

1.163 "**PV3.4**" means [***].

1.164 "**Quality Agreement**" has the meaning given in Section 8.3, hereto.

1.165 "**R&D Post-Transfer Period**" means the period from the transfer date from Atara to Partner of (a) the first Marketing Authorization or (b) if earlier, the first BLA or, at Partner's request, the IND, as applicable, in the United States for the Product by the FDA, in accordance with Section 6.1(a), or any other date agreed upon in writing between the Parties, onward during the Term.

1.166 "**R&D Pre-Transfer Period**" means, the period beginning on the Effective Date and ending upon the transfer date from Atara to Partner of (a) the first Marketing Authorization or (b) if earlier, the first BLA or, at Partner's request, the IND, as applicable, in the United States for the Product by the FDA, in accordance with Section 6.1(a), or any other date agreed upon in writing between the Parties

1.167 "**Receiving Party**" shall have the meaning given in Section 13.9(a), hereto.

1.168 "**Recission Notice**" has the meaning given in Section 16.2(a), hereto.

1.169 "**Regions**" means each of (i) the APAC Region, (ii) the European Region, (iii) the Eastern Europe Region, (iv) the Africa Region, (v) the Middle East Region, (vi) the LatAm Region, and (vii) the North America Region.

1.170 "**Regulatory Approval**" means, with respect to a Product in any country, region or jurisdiction, the approvals by the applicable Regulatory Authority in such country, region or jurisdiction necessary for the Commercialization and/or Manufacturing of such Product and including the approval by the applicable Regulatory Authority of any expansion or modification of the Label. For clarity, Regulatory Approval includes, but is not limited to, grant of a Marketing Authorization or a conditional Marketing Authorization.

1.171 "**Regulatory Authority**" means any applicable Government Authority responsible for granting Regulatory Approvals for the Product, including, without limitation, the FDA and any supra-national agency such as the EMA.

1.172 "**Regulatory Data**" means any and all pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data, natural history data, including source data, pharmacovigilance data, safety data, and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with regulatory filings for the Product in the Territory (including any applicable DMFs, CMC data, or similar documentation).

1.173 "**Regulatory Exclusivity**" means, with respect to a Product, that Third Parties are prevented by an applicable Regulatory Authority or country, region or jurisdiction from legally commercializing a product that could compete with such Product in a country, region or jurisdiction in the Territory other than through Patent Rights (inclusive of, for example, new biologic entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data or market exclusivity).

1.174 "**Regulatory Filings**" means, with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application specific to the Product and shall include any submission to a regulatory advisory board and any supplement or amendment thereto, including, without limitation, a BLA or MAA.

1.175 "**Regulatory Interactions**" means (a) all regulatory actions, communications and filings with, and submissions to, all Regulatory Authorities with respect to a Product, and (b) interfacing, corresponding and meeting with the Regulatory Authorities with respect to a Product.

1.176 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, conduct or have conducted Cell Selection, Manufacture (subject to the terms of this Agreement), have Manufactured, obtain Marketing Authorization, or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, MAAs, BLAs, presentations, and responses.

1.177 "**Released**" means, with respect to quantities of Manufactured Product or Product-Specific Intermediates, as applicable, that such quantities have been dispositioned by Atara as conforming with (i) the Product Specifications (as defined in the Original Manufacturing and Supply Agreement and the Original Quality Agreement or the MSA and the Quality Agreement, as applicable) or (ii) the specifications for the Product-Specific Intermediates, as applicable, and in compliance with applicable Regulatory Approvals, GMP and other applicable Laws.

1.178 "**Representative**" has the meaning in Section 13.1, hereto.

1.179 "**Restricted Products**" shall have the meaning given in Section 7.12, hereto.

1.180 "**Right of Reference**" shall have the meaning set forth in 21 C.F.R. §314.3(b) or equivalents thereto under applicable Law in countries, regions or jurisdictions outside the United States.

1.181 "**Royalty Report**" shall have the meaning given in Section 10.8(a), hereto.

1.182 "**Royalty Term**" means, on a country-by-country-basis within the Territory, the period beginning on the date of the First Commercial Sale of Product in such country and ending on the last to occur of (a) [***] after the First Commercial Sale in the applicable country; (b) the expiration or abandonment of the last Valid Claim of the Patent Rights within the Atara Intellectual Property that Covers any aspect of the Commercialization of the Product in the Field in such country; or (c) the expiration of all Regulatory Exclusivity for such Product in the Field in such country.

1.183 "**Safety Reasons**" shall have the meaning given in Section 15.5, hereto.

1.184 "**Sanctioned Country**" means Cuba, Iran, Syria, North Korea, and the Crimea Region of Ukraine, and any other country or region subject to comprehensive sanctions under applicable Law.

1.185 "**Sanctioned Person**" means any natural or legal person (i) identified on the Specially Designated Nationals and Blocked Persons List administered by the U.S. Department of Treasury Office of Foreign Assets Control (OFAC), on the Entity List, the Unverified List, or the Denied Persons List administered by the U.S. Department of Commerce Bureau of Industry and Security (BIS), or on any equivalent lists maintained by the United Nations; (ii) fifty percent (50%) or greater owned, directly or indirectly, in the aggregate, or otherwise controlled by a person or persons described in clause (i); or (iii) that is organized, resident, or located in a Sanctioned Country.

1.186 "**Schedule Review Period**" has the meaning given in Section 16.2(a), hereto.

1.187 "**SEC**" means the U.S. Securities and Exchange Commission.

1.188 "**Second Inventory Purchase**" has the meaning given in Section 8.6(b), hereto.

1.189 "**Selected Manufacturer**" has the meaning given in Section 8.5(c), hereto.

1.190 "**Subcommittee**" has the meaning given in Section 3.3(a), hereto.

1.191 "**Tax Documentation**" means, to the extent required to alleviate withholding on payments made by Partner to Atara under this Agreement, the applicable French tax forms number 5000 and 5003, as such forms may be amended from time to time in accordance with applicable Law duly stamped and validated by the relevant governmental entity with responsibility for taxes in connection with any tax reduction or exemption under any applicable international tax treaty between France and the U.S. French tax form number 5000 may be substituted with the applicable US Internal Revenue Service tax form number 6166.

1.192 "**Term**" has the meaning given in Section 15.1, hereto.

1.193 "**Terminated Country**" means each country that is the subject of a termination (a) by either Party pursuant to Section 15.2(a), or (b) by Partner pursuant to Section 15.4 (all such countries, collectively, the "**Terminated Countries**"). Each country included in a Terminated Region shall be deemed a Terminated Country.

1.194 "**Terminated Region**" means each Region that is the subject of a termination by Partner pursuant to Section 15.4.

1.195 "**Territory**" means, collectively, the Initial Territory and the Additional Territory, but not any Terminated Countries.

1.196 "**Third Party**" means any Person other than Atara, Partner and their respective Affiliates.

1.197 "**Transfer Election Date**" means January 31, 2024.

1.198 "**Transferred Contract**" means each contract set forth on the Transferred Contract List, provided that any such contract shall only constitute a Transferred Contract for so long as

such contract remains on the Transferred Contract List pursuant to the first sentence of Section 4.3.

1.199 "**Transferred Contract List**" means the list of contracts set forth in Schedule 1.199, as may be updated from time to time (a) prior to the Transfer Election Date, in accordance with Section 4.3, (b) after the Transfer Election Date, as specified in Schedule 1.199, and (c) otherwise by mutual written agreement of the Parties.

1.200 "**Transition Budget**" shall mean the overall budget of Transition Costs for conducting all activities under the Transition Plan, as prepared by Atara, with input from Partner, approved by the JSC, and as will be updated from time to time through the JSC. The Transition Budget shall include [***].

1.201 "**Transition Costs**" shall mean FTE Costs and Out-of-Pocket Costs incurred by Atara (including its Affiliates for such purpose) in carrying out its obligations under the Transition Plan, in each case to the extent incurred in accordance with this Agreement, the Transition Plan and the Transition Budget.

1.202 "**Transition Plan**" has the meaning given in Section 4.1(b), hereto.

1.203 "**Transition Services Agreement**" has the meaning given in Section 4.3(c), hereto.

1.204 "**United States**" or "**U.S.**" means the United States of America including its territories and possessions.

1.205 "**Upfront Payments**" has the meaning given in Section 10.1, hereto.

1.206 "**Valid Claim**" means (a) a claim of an issued and unexpired patent which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (b) a claim of a pending patent application which claim was filed in good faith, has not been pending for more than [***] from the priority date, and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

1.207 "**Wind-down Period**" has the meaning given in Section 15.7(b)(ii)(A), hereto.

ARTICLE 2
Licenses

2.1 **Grant to Partner**.

Subject to the terms and conditions of this Agreement, Atara hereby grants to Partner and its Affiliates (only for so long as each such Affiliate remains an Affiliate of Partner) during the Term:

(a) an exclusive (except as specified in Section 2.1(b) hereto), remuneration-bearing license (or sub-license, as applicable) with the right to sublicense only in accordance with Section 2.2 under the Atara Intellectual Property to research, Develop, make, have made, use, sell,

offer for sale and import the Product and any related companion diagnostics, and to conduct or have conducted Cell Selection, in the Field in the Territory. For clarity, with respect to Combination Products, the foregoing license applies only to the Product, and does not include any such rights with respect to any Other Components. Partner acknowledges that certain Know-How licensed to Atara by MSK under the MSK Agreement is licensed to Atara on a non-exclusive basis.

(b) **Reserved Rights.**

(i) Atara. Partner acknowledges and agrees that notwithstanding the exclusive rights granted to Partner hereunder, Atara shall retain, on behalf of itself, its Affiliates and Third Party designees, all other rights under the Atara Intellectual Property not specifically licensed to Partner under Section 2.1 including, without limitation, the right to (i) conduct and complete the Current Studies (until, with respect to each such study, the transfer thereof to Partner in accordance with Section 5.1(a) or the termination thereof in accordance with Section 6.5), and (ii) use or have used the Atara Intellectual Property for performing any and all of its obligations under this Agreement (including, without limitation, to conduct or have conducted Development, Cell Selection, regulatory, or Manufacturing activities for Product in the Territory), subject to the terms and conditions of this Agreement and the Ancillary Agreements.

(ii) Third Parties. The U.S. Government and Memorial Sloan Kettering Cancer Center have certain reserved rights pursuant to 35 U.S. Code § 200 et seq., and Section 2.4 of the MSK Agreement, respectively.

2.2 **Sublicenses**.

(a) Partner may sublicense (i) the right to seek and maintain Regulatory Approvals for the Product in the Field in the Territory during the Term in the Territory (except for during the R&D Pre-Transfer Period in the United States), if it is necessary under applicable Law for an Approved Sublicensee to hold any Regulatory Approval for the purpose of Commercializing the Product in the Field and in the Territory, (ii) the right to Commercialize the Product in the Field and in the Territory, and (iii) other rights necessary to research, Develop, Manufacture, make, have made, use and import the Product in the Territory, or to conduct or have conducted Cell Selection, in each case, without the prior consent of Atara, provided that (A) Partner shall only be entitled to grant the sublicenses to Third Parties referred to in subclauses (i) and (ii) in countries within the Major Markets to the extent it obtains the prior written consent of Atara (such consent not to be unreasonably withheld, conditioned or delayed), and (B) Partner shall only be entitled to grant the sublicenses of any right to manufacture (including the rights to make, have made and use, relating thereto) to Third Parties referred to in subclause (iii) to the extent it obtains the prior written consent of Atara (such consent not to be unreasonably withheld, conditioned or delayed, provided that Atara may not withhold, condition or delay such consent if such proposed sublicensee [***], *provided, further, that* the condition in subclause (2) shall not apply in case of a technology transfer of manufacturing activities resulting from the failure of the contract manufacturing organization that is responsible for performing such manufacturing activities under a Transferred Contract (each, an "**Approved Sublicensee**"); provided, however, (x) that all such sublicenses with an Approved Sublicensee shall be consistent with the terms of this Agreement, (y) that all such sublicense agreements must expressly provide that MSK is a third-party beneficiary with regard

to the provisions of Articles 11, 13 and 14 and Sections 6.1 and 7.6 of the MSK Agreement, and (z) that Partner shall be responsible for performance of Partner's responsibilities under this Agreement to the extent performed on the Partner's behalf by an Approved Sublicensee as if Partner were itself performing such activities. All Approved Sublicensees shall have the necessary financial, regulatory and technical capacity to carry out the portion of Partner's obligations under this Agreement sublicensed thereto and shall be required by Partner to perform all activities under this Agreement in compliance with the terms and conditions of this Agreement, any applicable Ancillary Agreement, and applicable Law. Should Partner sublicense or assign rights to an Affiliate hereunder in any Major Market country and such Affiliate subsequently becomes a non-Affiliate, Partner shall provide written notice to Atara within [***] of such change of such non-Affiliate's status and such non-Affiliate shall only be permitted to continue performance under the applicable sublicense or assignment if approved in writing by Atara, such approval not to be unreasonably withheld, conditioned or delayed. Countries for which Partner intends to use Approved Sublicensees are listed in Exhibit A hereto. Partner shall, within [***] after granting any sublicense under this Section 2.2 to a non-Affiliate, notify Atara of the grant of such sublicense and provide Atara with a true and complete copy of such sublicense agreement, provided that such copies of such sublicense agreements may be redacted to omit information (including, without limitation, financial terms) not directly relevant to the performance of Partner's obligations under this Agreement and in the case of an Affiliate, notify Atara of the grant of such sublicense and the identity of the Affiliate. For clarity, to the extent Partner engages a Third Party to provide services on behalf of Partner or its Affiliates (*e.g.*, a contract research organization) and fails to provide Atara a copy of the agreement with such Third Party, Partner shall promptly (and in any event, within [***] of Atara's request) provide a copy of such agreement to Atara, provided that such copy may be redacted to omit information (including, without limitation, financial terms) not directly relevant to the performance of Partner's obligations under this Agreement, as Atara's sole remedy (except if Partner fails to provide such copy within the applicable [***] of Atara's request therefor). Should it be necessary under applicable Law for an Approved Sublicensee to hold any Regulatory Approval for the purpose of Commercializing the Product in the Field and in the Territory, Partner shall provide prior written notice to Atara of such requirement. The filing of such Regulatory Approval [***]. If such Approved Sublicensee is otherwise acting in the capacity of a Distributor as set forth in Section 2.2(b), Section 2.2(a) shall not apply and the provisions of Section 2.2(b) (including the financial provisions) shall apply.

(b) Partner may appoint any wholesaler, distributor or reseller for the Product (collectively, the "**Distributors**") and grant them limited rights under Atara Intellectual Property solely to the extent needed to import, distribute, market, promote or sell the Product in the Field and the Territory, provided that any such appointment is made in a bona fide, arms-length transaction. When appointed, Partner shall use Distributors consistent with how Partner then commercializes its other oncology products in such countries, provided that in such countries in the Territory where Partner does not book the sales of a Product and elects to use Distributors, Partner uses as a basis for calculating royalty payments due to Atara under Section 10.4 [***]. All such distribution arrangements shall be consistent with the terms of this Agreement and shall require the Distributor to comply with all applicable Law, and Partner shall be responsible for performance of Partner's Commercialization responsibilities under this Agreement to the extent performed on the Partner's behalf by a Distributor as if Partner were itself performing such activities. Partner shall, within [***] after entering into a Product distribution agreement with a

Distributor, provide Atara with a true and complete copy of such Product distribution agreement, provided that such copies of such distribution agreements may be redacted to omit information (including, without limitation, financial terms) not directly relevant to the performance of Partner's obligations under this Agreement.

2.3 **No Other Rights or Implied Licenses.**

Except as specifically set forth in this Agreement, neither Party nor any of its Affiliates shall acquire any right, title, license, or other interest, by implication, estoppel or otherwise, with respect to any (a) information, Know-How or materials of the other Party or its Affiliates disclosed or provided to it under this Agreement or (b) under any Patent Rights or other intellectual property rights owned or Controlled by the other Party or its Affiliates.

2.4 **Restrictive Covenants**.

(a) **Ex-Field Activities and Field Activities**.

(i) To the extent permitted by applicable Law, Partner hereby covenants and agrees that it shall not (and shall ensure that its Affiliates Approved Sublicensees, and Distributors shall not), either directly or indirectly, sell, market or promote the Product for use outside the Field. Without limiting the generality of the foregoing, Partner shall not (i) engage in any promotional, advertising, market research, educational, scientific communications, medical affairs, or similar activities relating to the Product directed to use outside the Field, or (ii) solicit orders from any prospective purchaser for use of the Product outside the Field.

(ii) To the extent permitted by applicable Law, except with respect to the activities contemplated hereunder and in addition to the restrictions set forth in Section 7.12, Atara hereby covenants and agrees that it shall not (and shall ensure that its Affiliates, distributors, and sublicensees shall not), either directly or indirectly, sell, market or promote the Product for use inside the Field. Without limiting the generality of the foregoing, Atara shall not, except in the performance of its obligations under this Agreement or any Ancillary Agreements, (i) engage in any promotional, advertising, educational, scientific communications, medical affairs or similar activities relating to the Commercialization of the Product inside the Field, or (ii) solicit orders from any prospective purchaser for use of the Product inside the Field.

2.5 **MSK Agreement**.

The licenses and rights granted to Partner under Section 2.1 above include sublicenses of Know-How and Patent Rights existing and licensed to Atara under the MSK Agreement. Any royalty, milestone and other amounts payable to Third Parties in relation to the licenses granted by Atara under Atara Intellectual Property hereunder, including pursuant to the MSK Agreement, shall be paid by Atara.

ARTICLE 3
Joint Steering Committee

3.1 **Composition.**

Pursuant to the Original Commercialization Agreement, the Parties have, prior to the Execution Date, established a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") as more fully described in this Article 3, comprised of three (3) representatives (or such other number as the Parties may agree to) of appropriate seniority and experience to serve on the JSC, designated by written notice of each Party to the other Party. Either Party may designate substitutes for its representatives if one (1) or more of such Party's designated representatives are unable to be present at a meeting. From time to time, each Party may replace its representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). A quorum of the JSC shall exist whenever there is present at a meeting at least two (2) representatives appointed by each Party. The JSC will be co-chaired by one representative each of Partner and Atara. The role of the chairpersons shall be to convene and preside at meetings of the JSC. The chairpersons shall have no additional powers or rights beyond those held by the other JSC representatives. Each Party may also, in its reasonable discretion and with reasonable advanced notice to the other Party, invite a reasonable number of non-member representatives of such Party to attend JSC meetings, as appropriate, to provide input with respect to matters on the agenda.

3.2 **Responsibilities.**

In addition to such other duties as specifically assigned to it in this Agreement, in order to facilitate effective transition from Atara to Partner of all Development, Cell Selection, regulatory activities, Manufacturing and Commercialization of the Product in the Field in the Territory, during the Term, until the JSC Termination Date, the JSC shall:

(a) monitor the general performance of the Parties under this Agreement and decide on corrective action, where required;

(b) serve as the principal means by which each Party keeps the other Party informed about respective activities under the Agreement;

(c) act as the initial point of escalation for issues that cannot be resolved otherwise;

(d) monitor and coordinate the conduct of the Transition Plan;

(e) review, propose and update the Transition Plan, including the Transition Budget set forth therein and the allocation of responsibilities between the Parties, as needed, but no less frequently than once each calendar half-year;

(f) receive reports relating to, review and discuss the progress of, any ongoing Development activities of the Product, including the conduct by Atara of Atara 302 Study and the

Atara 205 Study, including any proposed study protocols and proposed substantive amendments and updates and any activities conducted pursuant to Sections 5.1(a), 5.1(b), and 5.1(c) hereof;

(g) receive reports relating to, review and discuss the progress of, and approve (solely with respect to the R&D Pre-Transfer Period) material submissions to, or material actions taken with, the FDA pertaining to the Product, including, without limitation, Regulatory Interactions, BLA, and Marketing Authorizations, either in advance or thereafter as determined by required timing for making such material submissions or taking such material actions;

(g) receive reports relating to, and review and discuss Manufacturing and commercial supply plans pertaining to the Product in the Territory including any plans to ensure a continuous and reliable supply of Product in the Territory and approve, as required by the provisions of this Agreement, substantive changes in the supply chain of the Product;

(h) subject to Section 7.8 hereto, review and discuss a transition of Cell Selection services from Atara to Partner, its Affiliate or an Approved Sublicensee;

(i) review and discuss patent strategies and prosecution, defence and enforcement actions in relation to the Atara Intellectual Property; and

(j) discuss and coordinate any action with respect to alleged infringement of Third Party Patent Rights by Commercialization of the Product in the Field in the Territory, or the Development or Manufacture of the Product for Commercialization in the Field in the Territory; and

(k) provide a forum of exchange and discussion with respect to medical affairs and Commercialization activities, transition and related matters.

3.3 **Subcommittees Establishment.**

(a) From time to time, during its existence, the JSC has and may further formally establish one or more subcommittees to review and make recommendations to the JSC with respect to particular projects or activities within their respective authority (each, a "**Subcommittee**"). In advance of the Execution Date, the JSC established a joint product team Subcommittee, a joint commercial Subcommittee, a joint development/regulatory Subcommittee, a joint safety Subcommittee, and a joint Product manufacturing and supply Subcommittee. Each Subcommittee does and shall consist of equal representation from the Parties (unless the Parties otherwise mutually agree) consisting of individuals with relevant expertise. Such Subcommittees shall operate under the same principles and requirements as are set forth in this Article 3 for the JSC.

(b) Within [***] following the Effective Date, the JSC shall formally establish a subcommittee in order to facilitate and oversee the Development and regulatory activities relating to Manufacturing PV3.3 and PV3.4, as described in Section 8.2, and the effective transition of such Manufacturing processes for the Product from Atara to Partner (such Subcommittee, the "**Manufacturing Working Group**" or "**MWG**").

3.4 **Meetings.**

The JSC shall hold meetings (a) [***], and (b) at the reasonable request of either Party upon as much reasonable notice as is practicable, but not less than [***] prior written notice to the other Party, to review, discuss, or approve, as applicable, an urgent matter within the scope of the JSC's responsibilities, in each case, at such times and places as shall be determined by the JSC (including by videoconference, telephone, or web conference). The JSC may act without a meeting if prior to such action a written consent thereto is given by both Parties. Each Party shall be responsible for all its costs incurred for attending and participating in JSC meetings.

3.5 **Minutes.**

Minutes will be kept of all JSC meetings by the Alliance Managers and the minutes prepared by the Alliance Managers will be sent to all members of the JSC for review and approval within [***] after each meeting. Minutes for each meeting shall objectively reflect, in reasonable detail, the proceedings of such JSC meeting, including, without limitation, the topics reviewed and discussed at such JSC meeting, and the actions and decisions taken, authorized to be taken or approved to be taken by either or both of the Parties at such meeting. In the event of any objection that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute and such dispute shall be reviewed and discussed at the next regular JSC meeting.

3.6 **Alliance Managers.**

Pursuant to the Original Commercialization Agreement, prior to the Execution Date, each Party appointed a representative of such Party to act as its alliance manager under this Agreement (each, an "**Alliance Manager**"). Each Party may replace its Alliance Manager at any time by written notice to the other Party. The Alliance Managers will serve as the primary contact point between the Parties and shall be entitled to attend all JSC and Subcommittee meetings, except if the other Party specifically requests the exclusion of Alliance Managers (including its own Alliance Managers) from a particular meeting. Each Alliance Manager may bring any matter to the attention of the JSC or Subcommittees where such Alliance Manager reasonably believes that such matter requires attention of the JSC or Subcommittees. Each Alliance Manager shall be responsible with creating and maintaining a collaborative work environment within and among the JSC and Subcommittees.

3.7 **Scope of Governance.**

Notwithstanding the creation of the JSC and/or any Subcommittee, each Party shall retain the rights, powers and discretion granted to it hereunder, and the JSC and/or any Subcommittee shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. The JSC and/or any Subcommittee or any Party's exercising its decision making shall not have the power to amend or modify this Agreement, and no decision of the JSC and/or any Subcommittee or a Party's exercising its decision making shall be in contravention of any terms and conditions of this Agreement. The Alliance Managers shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder and in no event shall the Alliance

Managers have any power to modify or amend this Agreement. It is understood and agreed that issues to be formally decided by the JSC and/or any Subcommittee, as applicable, are only those specific issues that are expressly provided in this Agreement to be decided by the JSC and/or any Subcommittee, as applicable.

3.8 **Decision Making.**

(a) **Generally**. Except as otherwise expressly provided herein, decisions of the JSC or any Subcommittee established under this Article 3 shall be made by consensus, with each Party having collectively one (1) vote in all decisions, with the goal being to leverage capabilities, minimize cost and maximize the chance of successfully Commercializing the Product first in the Major Markets as a whole, and then throughout the Territory as a whole, in a manner consistent with applicable Laws and this Agreement. The Parties agree to make all decisions and, where a unanimous decision cannot be reached, to escalate all associated disputes, in a timely manner, appropriate for each circumstance.

(b) **Dispute Escalation and Final Decision-Making Authority**. In the event that the JSC is unable to reach a consensus on decisions expressly requiring JSC approval pursuant to this Agreement, or following the JSC Termination Date if the MWG is unable to reach a consensus on a decision within its purview, despite good faith efforts to do so within [***] after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to the Chief Executive Officer of Atara or such other person holding a similar position designated by Atara from time to time, and the Chief Executive Office of Partner or such other person holding a similar position designated by Partner from time to time (collectively, the "**Executive Officers**"), for resolution. The Executive Officers shall meet within [***] of referral of the issue to the Executive Officers to discuss the matter submitted and to determine a resolution. If the Executive Officers are unable to determine a resolution in a timely manner, which shall in no case be more than [***] after the matter was referred to them, despite good faith efforts to do so, then except as specifically allocated under this Agreement:

(i) Atara shall have final decision-making authority with respect to all matters directly relating to [***]

(ii) Subject to Section 3.8(b)(i) and Article 7, Partner shall have final decision-making authority with respect to [***]. Without limiting the foregoing, Partner shall have final decision making authority on all matters directly relating to: [***].

3.9 **Termination of the JSC**

(a) The JSC shall be terminated and dissolved upon the JSC Termination Date, provided that following such termination and dissolution, the Parties shall meet on [***] to share information regarding the Development of the Product in the Territory (including, without limitation, Development timelines and Partner's efforts to obtain Regulatory Approval for the Product in the Major Markets and throughout the Territory) and Commercialization of the Product in the Territory. For clarity, at each such meeting, Partner shall provide to Atara an update of its Development and Commercialization activities and plans.

(b) Notwithstanding Section 3.9(a), following the JSC Termination Date and until Partner has obtained Regulatory Approval for PV3.3 and PV3.4 for the Manufacturing of the Product in the US and EU, or prior thereto upon mutual agreement of the Parties (such period, the "**New Manufacturing Process Transition Period**"), the Manufacturing Working Group shall remain in place to facilitate the effective transition of the PV3.3 and PV3.4 Manufacturing processes for the Product from Atara to Partner. During the New Manufacturing Process Transition Period, the MWG shall continue to meet periodically, as mutually agreed by the Parties, to discuss the Development and regulatory activities relating to Manufacturing PV3.3 and PV3.4, as described in Section 8.2. [***].

ARTICLE 4
Transition Plan

4.1 **Transition Plan.**

(a) **Prior Transfer**. Pursuant to the Original Commercialization Agreement, the Parties mutually agreed upon and carried out all activities under a transition plan for certain commercial, regulatory, Development, and technical operations activities relating to the Initial Territory.

(b) **General**. An initial transition plan for certain commercial, regulatory, Development, and technical operations activities to be carried out under this Agreement and the Ancillary Agreements with respect to the Territory (including, without limitation, the Additional Territory) is attached hereto as Exhibit B together with the Transition Budget related therewith for carrying out the Transition Plan (the "**Initial Transition Plan**"). The Initial Transition Plan (including the Transition Budget) may be updated from time to time through the JSC, *provided that*, notwithstanding anything to the contrary herein, to the extent any such updates to the Transition Plan may result in any new, increased, or extended obligation of, liability for, or cost to Atara, (i) subject to Section 10.11(d), the Transition Budget will be increased to reasonably correspond to such updates in the Transition Plan, and (ii) any changes to Atara's obligations resulting from such updates will be subject to Atara's available capacity and capabilities (as so updated, the "**Transition Plan**").

(c) **Allocation of Transition Activities**. The Transition Plan shall allocate responsibility between the Parties for the various transition activities addressed in the Transition Plan. Atara shall use Commercially Reasonable Efforts to incur only reasonable costs to carry out the activities as specifically set forth in the Transition Plan pursuant to the provisions of and within the timelines set forth in the Transition Plan.

(d) **Diligence Efforts**. Each Party shall use its Commercially Reasonable Efforts to perform the activities assigned to it under the Transition Plan and Atara shall make available to Partner all data and such other documents as set forth under the Transition Plan as soon as reasonably practicable and in any event, within the time period set forth in the Transition Plan. Each Party shall conduct such activities in good scientific manner and in compliance with all applicable Laws, including applicable Laws regarding the environment, safety and industrial hygiene, and GMP, GLP, GCP, informed consent and Institutional Review Board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the

protection of human subjects.

4.2 **Subsequent Transfers**. Before the transfer date from Atara to Partner of the Marketing Authorization or BLA (in advance of its approval), as applicable, by the FDA, Atara shall deliver as soon as reasonably practicable any and all Know-How constituting Atara Intellectual Property, together with supporting documentation as each may become Controlled by Atara, and provide reasonable assistance to Partner which is necessary or reasonably useful for Partner to research, Develop, make, have made, use, sell, offer for sale and import the Product, as well as to conduct or have conducted Cell Selection in the Field and the Territory, in compliance with Law. Besides the Transition Plan, Atara shall provide reasonable assistance to Partner, subject to Atara's available capacity and capabilities to provide such assistance, to ensure a smooth and effective transfer of any Regulatory Filings, Know-How constituting Atara Intellectual Property, Development Data, medical activities and marketing materials developed by Atara with respect to the Product.

4.3 **Transferred Contracts**. On or prior to the Transfer Election Date, the Parties shall amend the Transferred Contracts List to remove any contracts that Partner does not wish to assume and for which Atara will have no obligation to assign such contract to Partner. For clarity, with respect to any such contract that is removed from the Transferred Contracts List, upon the applicable Assignment Date for such contract, (a) Atara shall be relieved of any obligations under this Agreement with respect to such contract, and any corresponding activities assigned to Atara under the Transition Plan (which activities will be the Partner's sole responsibility) and (b) such contract will no longer be a Transferred Contract, and such contract will not be subject to this Section 4.3. Following the Transfer Election Date, Atara shall transfer and assign to Partner and Partner shall assume, pursuant to an assignment and assumption agreement in customary form, all Transferred Contracts as follows:

(a) with respect to the Transferred Contracts that relate solely to the Product (and no other products or product candidates), such assignment and transfer shall occur upon the applicable date specified in Schedule 1.199 (attached hereto) for each such Transferred Contract; and

(b) with respect to all other Transferred Contracts, Atara shall (i) use Commercially Reasonable Efforts to negotiate with each applicable counterparty a bifurcation of the applicable Transferred Contract, so as to separate the terms of such Transferred Contract that are applicable to the Product into a separate agreement that contains materially the same terms (as applicable to such Product) as such Transferred Contract. Partner shall have a reasonable opportunity to review and comment on the final draft and any material iteration prior to such final draft of such separate agreement prior to Atara's execution thereof, in accordance with the Transition Plan, (upon such bifurcation, each such Product-specific agreement, a "**Bifurcated Contract**"), and (ii) with respect to each Bifurcated Contract, such assignment and transfer shall occur on the later of: (A) the applicable date specified in Schedule 1.199 (attached hereto), or (B) the date of such bifurcation.

(c) If Atara (i) is not able to bifurcate any Transferred Contract described in Section 4.3(b), or (ii) is not able to obtain any third party consent required for the assignment of any Transferred Contract described in Section 4.3(a), despite having used Commercially

Reasonable Efforts to do so, then, in each case (i) and (ii), subject to the Parties entering into a commercially reasonable, mutually-agreed transition services agreement (the "**Transition Services Agreement**"), (A) Atara shall retain the rights under each such Transferred Contract as are reasonably necessary thereunder to provide Partner with the relevant goods or services under such Transferred Contracts, so that Partner or its Affiliate or designee shall be entitled to the economic rights and benefits relating to the Products thereunder, and provided that Partner shall bear any and all duly documented Out-of-Pocket Costs incurred by Atara associated therewith, [***], and (B) during the term of the Transition Services Agreement, Atara shall use Commercially Reasonable Efforts to provide Partner, at Atara's costs, with reasonable assistance (*e.g.*, by making introduction to the relevant Third Party) in Partner's negotiation of new Third Party arrangements for the provision of comparable goods or services as those provided to Atara under such Transferred Contracts.

ARTICLE 5
Development Matters

5.1 **Responsibilities – Current Studies and Other Clinical Studies.**

(a) During the applicable period specified in the Transition Plan, Atara shall be responsible, at Partner's sole cost and expense (including, without limitation, costs for distribution and logistics of Product) in accordance with the Transition Budget related therewith, to use Commercially Reasonable Efforts to conduct the Atara 302 Study and the Atara 205 Study, each as currently designed and ongoing as of the Execution Date, provided that, during the R&D Pre-Transfer Period, Partner shall provide and allocate to Atara appropriate quantities of Product, within the quantities transferred by Atara to Partner pursuant to Sections 8.5(a) and 8.6(a), as required for the conduct of such Current Studies. Notwithstanding the foregoing, Atara will provide, at any time within [***] after Partner's written request therefor, the right for Partner to assume sole responsibility for the Atara 302 Study and the Atara 205 Study, each as currently designed and ongoing as of the Execution Date, in accordance with the Transition Plan. For clarity, Partner shall reimburse Atara for all costs, including any and all Out-Of-Pocket Costs and FTE Costs, including, for example, all Product Development costs (e.g., clinical operations, clinical sciences, biostatistics, data management, and medical writing) and Product safety and translation activities incurred in connection with the conduct and/or transfer to Partner of such studies in accordance with the Transition Budget.

(b) Upon the date on which Atara transfers responsibility for conducting the Atara 302 Study and the Atara 205 Study to Partner as specified in Section 5.1(a), and thereafter, Partner shall be solely responsible, at its sole cost and expense, to use Commercially Reasonable Efforts to (i) conduct the Atara 302 Study as currently designed and ongoing as of the Effective Date, (ii) fully enroll and conduct stage one of the Atara 205 Study as currently designed and ongoing as of the Effective Date, [***].

(c) Partner shall be solely responsible, at its sole cost and expense, to use Commercially Reasonable Efforts to conduct any other Clinical Study or other Development that is required by the Regulatory Authority to obtain and maintain Regulatory Approval for the Product in the Field in the Territory. Partner shall promptly inform Atara of any Development Data generated therefrom and provide such Development Data to Atara pursuant to Section 5.4.

(d) For clarity, other than as set forth in Section 5.1(a), Atara shall have no obligation to conduct any Clinical Study or any Development for the Product in the Field in any country, region, or jurisdiction.

5.2 **Reports**.

Prior to the JSC Termination Date, the status, progress and results of the Development carried out under this Article 5 shall be discussed at meetings of the JSC, and the responsible Party shall provide the JSC with a written report with reasonable detail on the status and progress of such Development activities at least [***] prior to each scheduled JSC meeting. Following the JSC Termination Date, the status, progress and results of the Development carried out under this Agreement shall be discussed at the [***] set forth in Section 3.9(a).

5.3 **Records.**

The Party carrying out Development activity shall use Commercially Reasonable Efforts to maintain complete, current and accurate records of all Development conducted by it and all Development Data resulting from such work. The Parties shall cause their Affiliates, sublicensees and subcontractors (as applicable) to maintain complete, current and accurate records of all Development work conducted by such Affiliates, sublicensees or subcontractors (as applicable) and data and other Information resulting from such work. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory purposes.

5.4 **Ownership of Development Data and Partner Inventions.**

(a) All data (including, without limitation, pre-clinical, clinical, technical, chemical, safety, and scientific data and information, including a closed portion of a DMF Controlled by a Party and in accordance with applicable Law) and other results, all as related to the Product, generated hereunder, by or resulting from or in connection with the conduct of Cell Selection, Development, including screening data, Regulatory Data and synthesis schemes (collectively, the "**Development Data**"), shall be owned solely and exclusively by Partner, provided that Partner shall and hereby does grant to Atara a non-exclusive, fully paid-up, sublicensable (through multiple tiers) and irrevocable (except in the event of a termination of this Agreement in its entirety) license under any and all such Development Data to perform its obligations hereunder. Subject to the foregoing license grant from Partner to Atara, Atara hereby assigns to Partner all Development Data deriving from any and all Development conducted by Atara (or conducted on behalf of Atara, solely to the extent Atara owns such Development Data) before or under this Agreement to the extent necessary or reasonably useful for Partner to research, Develop, make, have made, use, sell, offer for sale and import the Product for distribution and use in the Field in the Territory, as well as to conduct or have conducted Cell Selection in the Field in the Territory

(b) To the extent that Partner, in the course of conducting any of its authorized activities under this Agreement, has developed and Controls Patent Rights or Know-How that are necessary or reasonably useful for the Development, Manufacture, Commercialization, or other use of the Product ("**Partner Intellectual Property**"), Partner shall grant to Atara [***].

5.5 **Right to Audit Development Activities.**

During the Term, subject to the requirements of applicable Law and Third Party confidentiality restrictions or obligations (provided that each Party shall use reasonable efforts to ensure that any Third Party agreements entered into after the Execution Date do not prevent the exercise of such rights), each Party shall allow the other Party's authorized Representatives, to the extent permitted by applicable Law, during regular business hours and upon at least [***] prior notice, not more than [***], to (i) examine and inspect such Party's facilities and the facilities of any subcontractor used in the performance of Development of the Product in the Field in the Territory hereunder, and (ii) inspect all data, documentation and work product relating to the activities performed by such Party or any subcontractor.

5.6 **Right of Reference.**

Each Party shall have the right to cross-reference the Regulatory Filings and DMF Controlled by the other Party under this Agreement relating to the Product (including each other's, and their Affiliate's or, in the case of Partner, its Approved Sublicensees'), and to access such Regulatory Filings, DMF and any Development Data for (i) in the case of Partner, during the Term, any activity relating to obtaining or maintaining Regulatory Approval for the Product, or for Development or Commercialization of the Product in the Field in the Territory, including, to the extent allowed under applicable Law, inclusion of such Development Data in its own Regulatory Filings for the Product, and (ii) in the case of Atara, (A) conducting the Current Studies and any other activity relating to conducting Development of the Product or obtaining or maintaining Regulatory Approval for the Product on behalf of Partner in accordance with this Agreement, and (B) [***]. Subject to the provisions of this Section 5.6, each Party hereby grants to the other Party, its Affiliates, subcontractors (as applicable), a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any Development Data, including such Party's or its Affiliate's clinical dossiers, Controlled by such Party or such Affiliates that relates to the Product solely for use for the purposes specified in this Section 5.6.

ARTICLE 6
Regulatory Matters

6.1 **Obtaining Regulatory Approval.**

(a) **United States – Primary Indication**. During the R&D Pre-Transfer Period, Atara shall be responsible, at Partner's sole cost and expense in accordance with the Transition Budget, for all activities directed to obtaining Regulatory Approval (including the preparation and filing of all Regulatory Materials, including, without limitation, any BLA, and all Regulatory Interactions and site inspections) for the Product for the Primary Indication in the United States; provided, however, that Atara shall promptly submit to Partner all material correspondence received from a Regulatory Authority with respect to such Regulatory Approvals, as well as all relevant draft filings or draft material correspondence with the Regulatory Authorities with reasonable lead time, which shall not be less than [***] for correspondence with the FDA relating to negotiation of the Label, to allow Partner to comment on such drafts, and take into account Partner's reasonable comments on such correspondence or filings. To the extent practical

and without causing any undue delay, and to the extent permitted by the Regulatory Authority, Atara shall permit an appropriate representative of Partner to attend any meeting with Regulatory Authorities relating to filing or obtaining such Regulatory Approvals as a silent observer under Atara's supervision. Notwithstanding the foregoing, Atara will provide, at any time within [***] after Partner's written request therefor, the right for Partner to assume sole responsibility for obtaining Regulatory Approval (including the preparation and filing of all Regulatory Materials, including, without limitation, any BLA, and all Regulatory Interactions) for the Product for the Primary Indication in the United States, and Atara shall transition to Partner all activities related thereto in accordance with a mutually agreed transition plan.

(b) **Other Regulatory Approvals**. With the exception of activities under Atara's responsibility pursuant to Section 5.1 and other than those specified in Section 6.1(a), Partner, its Affiliates and their Approved Sublicensees shall be responsible, at their sole cost and expense, for all activities directed to or required for obtaining, holding, and maintaining all Regulatory Approvals (including, without limitation, for the preparation and filing of all Regulatory Materials and all Regulatory Interactions) and Marketing Authorizations for the Product in the Field in the Territory, subject to the oversight of the JSC during the R&D Pre-Transfer Period, in accordance with Section 3.8 hereto, and subject to Section 3.9 in the R&D Post-Transfer Period. Atara will provide, at any time within [***] after Partner's written request therefor, the right for Partner to assume sole responsibility for the preparation and filing of all Regulatory Materials, including, without limitation, any BLA, and all Regulatory Interactions for the Product in regards to the Atara 302 Study and the Atara 205 Study, in accordance with the Transition Plan. If Partner reasonably believes that there exists sufficient clinical data to support such a filing and it is commercially reasonable to do so, Partner shall use Commercially Reasonable Efforts to file (i) a BLA for a Multi-Cohort Indication in the United States, and (ii) a MAA for a Multi-Cohort Indication in the EMA. Partner, its Affiliates and their Approved Sublicensees shall own all regulatory submissions, including all applications, for Regulatory Approvals for the Products in the Field in the Territory.

(c) **Reports**. The status, progress, and results of a Party's efforts to obtain Regulatory Approval for the Product under this Article 6 shall be discussed at meetings of the JSC during the R&D Pre-Transfer Period and as set forth in Section 3.9 thereafter, and each Party shall provide the JSC during the R&D Pre-Transfer Period (and Partner shall provide to Atara, as set forth in Section 3.9 after the R&D Pre-Transfer Period) with a written report on the status and progress of such activities at least [***] prior to each scheduled JSC meeting or [***] meeting, as applicable. In addition, a Party shall make available such information about such activities as may be reasonably requested by the other Party from time to time.

6.2 **Transfer of Marketing Authorization for the United States – Primary Indication**

Following the FDA's grant of a Marketing Authorization for the Product for the Primary Indication in the United States, unless responsibility for the Current Studies had already been transferred to Partner pursuant to Section 5.1(a), and in accordance with the Transition Plan, the Parties agree to take all required actions, and submit all required documentation, necessary for the transfer of the associated Marketing Authorization, the Orphan Drug Designation and any other necessary Regulatory Approval for the Product in the United States, to Partner within [***] of

receipt of said Marketing Authorization, unless otherwise agreed between the Parties and subject to applicable regulatory requirements. Prior to such transfer, Atara shall hold the Marketing Authorization and neither Atara nor Partner shall initiate Commercial Sale of Product in the United States until completion of such transfer other than responding to orders pursuant to any existing EAP in accordance with this Agreement. Subsequent to the transfer of the Marketing Authorization by Atara to Partner under this Section 6.2, Partner shall be responsible, at its sole cost and expense, for all activities directed or required to holding and maintaining such Marketing Authorization including, without limitation, for payment of all associated fees and taxes, if any. Notwithstanding any provision to the contrary in this Section 6.2, within [***] after Partner's written request therefor, Atara will provide to Partner the rights for Partner to assume sole responsibility for preparing the Regulatory Filings for the Product in the United States, subject to the Transition Plan.

6.3 **Pharmacovigilance.**

At a mutually agreeable time during the R&D Pre-Transfer Period, the Parties will negotiate and execute in good faith an amendment to the Original Pharmacovigilance Agreement (as amended, the "**Pharmacovigilance Agreement**") delineating the processes and procedures for sharing safety information with respect to the Product throughout the Territory (including the Additional Territory) and subsequently transferring responsibility for the Global Safety Database to Partner. The Pharmacovigilance Agreement shall, among other things, require each of Atara and Partner to inform the other as soon as is practicable of any observed significant safety issue considered likely to have an adverse impact on Commercialization of the Product.

6.4 **Global Safety Database.**

(a) **Responsibility**. Prior to the Execution Date, Atara has established and maintained a Global Safety Database that contains and will contain all information and data arising from the Parties' activities with respect to safety matters that is required to be contributed by each party pursuant to the Original Pharmacovigilance Agreement, including information and data arising out of any risk evaluation and mitigation strategy (REMS) and/or risk management plan (RMP), periodic safety reports and safety monitoring activities. Atara shall (i) continue to maintain such Global Safety Database during the R&D Pre-Transfer Period, and (ii) upon the end of the R&D Pre-Transfer Period, transfer such Global Safety Database to Partner. During the R&D Post-Transfer Period, and notwithstanding anything to the contrary contained in the Original Pharmacovigilance Agreement, Partner shall be solely responsible for maintaining such Global Safety Database.

(b) **Reporting**. Subject to the subsequent sentence, Partner shall be responsible for collecting and submitting safety case reports to the applicable Regulatory Authorities for all countries of the Territory. During the R&D Pre-Transfer Period, Atara or Atara's designee shall be responsible for collecting and submitting safety case reports to the applicable Regulatory Authorities for the United States, as applicable. Each Party shall share all safety case reports with the other Party pursuant to the terms of the Pharmacovigilance Agreement.

6.5 **Early Access Programs.**

Atara shall use Commercially Reasonable Efforts to continue conducting (and shall continue to conduct when required under applicable Law in any country, region or jurisdiction, as applicable, in the Territory), the Atara 902 EAP Observational Study in the Territory during the R&D Pre-Transfer Period. Unless otherwise agreed between the Parties through the JSC, Atara shall be responsible for operationally managing and conducting the Atara 902 EAP Observational Study throughout the Territory, [***]. Partner shall be responsible, at its sole cost and expense, for continuing to conduct the Atara 902 EAP Observational Study during the R&D Post-Transfer Period, if applicable, and any other Early Access Programs for Product in the Territory after the Effective Date, provided, however, Partner may not initiate or conduct any Early Access Program activities relating to the Primary Indication in the United States prior to obtaining Marketing Authorization for the Product for the Primary Indication in the United States.

6.6 **Regulatory Audits.**

The Parties shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility, including, without limitation, where Clinical Studies, CMC, or pharmacovigilance activities with respect to the Product are conducted by or on behalf of a Party pursuant to this Agreement, whether such site or facility is such Party's or its Affiliate's or Approved Sublicensee's, subject to terms and conditions of Third Party agreements (provided that each Party shall use reasonable efforts to ensure that Third Party agreements do not prevent the exercise of such rights), and shall inform each other of such Regulatory Authority inspection within [***] from its notification. Each Party shall be given a reasonable opportunity (taking into account the timing and notice provided by the applicable Regulatory Authority) to assist in the preparation of the other Party's audited sites for inspection, where appropriate, and to attend any inspection by any Regulatory Authority of the other Party's audited sites, and the summary, or wrap-up, meeting with a Regulatory Authority at the conclusion of such inspection. If such attendance would result in the disclosure to the other Party of Confidential Information unrelated to the subject matter of this Agreement, the Parties shall enter into a confidentiality agreement covering such unrelated subject matter. In the event that any audited site is found to be non-compliant with one or more GLP, GCP, or current standards for pharmacovigilance practice, the non-compliant Party shall submit to the other Party a proposed recovery plan within a reasonable period after such non-compliant Party, its Affiliate, its subcontractor, or its Approved Sublicensees receives notification of such non-compliance from the relevant Regulatory Authority and such non-compliant Party shall use Commercially Reasonable Efforts to implement such recovery plan promptly after submission. Partner shall reimburse Atara for all costs including any and all actual and documented Out-Of-Pocket Costs incurred by Atara pursuant to this Section 6.6 (including prior to the expiration of the R&D Pre-Transfer Period).

ARTICLE 7
Commercialization and Promotion Matters

7.1 **Responsibilities.**

Subject to Section 7.2 hereto, during the Term, Partner shall be solely responsible, at is sole cost and expense, for Commercializing the Product and all medical affairs related activities in each country in the Territory in accordance with this Agreement and with all applicable Laws, as provided herein.

7.2 **Diligence.**

Partner shall utilize Commercially Reasonable Efforts to perform its obligations and to carry out its responsibilities under this Agreement with respect to the Commercialization of the Product in the Field in the Primary Indication and in any other indication, in each case if and when Regulatory Approval and Pricing Approval of the Product is obtained for such indication(s), [***]. Partner agrees to use reasonable efforts to assess Commercialization opportunities for the Product in the Primary Indication in all other countries in the Territory.

7.3 **Initial Commercialization Outline.**

(a) Pursuant to the Original Commercialization Agreement, prior to the Execution Date, Partner presented to the JSC an outline of its Commercialization plans for the Product in the Initial Territory including Product positioning and planned branding, marketing strategy, advertising, pricing, reimbursement and launch sequencing, high-level annual sales projections, global budget, and presentation plans outside the Initial Territory.

(b) Within a reasonable period of time of the Effective Date, but in any case no later than within [***] prior to the Parties' estimated Marketing Authorization approval date of the Product for the Primary Indication in the United States, Partner will present an outline of its Commercialization plans for the Product in the U.S., including Product positioning and planned branding, marketing strategy, advertising, pricing, reimbursement and launch sequencing, high-level annual sales projections, and global budget.

(c) After (a) and (b) events, Partner will provide for the Territory, an update of its Commercialization activities on at least [***], for discussion by the JSC if it occurs during the R&D Pre Transfer Period, and as set forth in Section 3.9 if it occurs thereafter.

7.4 **Pricing.**

Partner shall, at its sole cost and expense, be solely responsible for obtaining and maintaining Pricing Approvals in the Territory where applicable and subject to Section 7.2, Partner shall use Commercially Reasonable Efforts to obtain Pricing Approvals where applicable in each of [***], subject to review and discussion by the JSC during the R&D Pre-Transfer Period under Section 3.2 hereto, taking into account [***]. Partner shall also be solely responsible, at its sole cost and expense, for setting and managing local pricing and reimbursement, as well as Product launch sequencing, subject to review and discussion by the JSC during the R&D Pre-Transfer Period, and as set forth in Section 3.9 thereafter. To the extent permitted by applicable Law, and unless necessary for the purpose of obtaining Pricing Approval for the Product in any country in the Territory, Partner shall not publicly disclose information on discounts and rebates relating to the pricing of Product in such country in the Territory.

7.5 **Promotional Materials.**

Partner shall, at its own expense, have the right to create, develop, produce or otherwise obtain, and utilize Promotional Materials to support the Commercialization of the Product in the Field in the Territory in accordance with applicable Laws.

7.6 **Ownership and Use of Product Trademarks and Product Trade Dress.**

(a) **Assignment of Product Trademarks.** Subject to the terms of this Agreement (including, without limitation, Section 15.7(b)(iii)(C)), Atara hereby assigns to Partner all Product Trademarks, Product Trade Dress, and Product-specific website domain names used or intended to be used specifically in connection with the Commercialization of the Product for the Field in the Territory to Partner.

(b) **Maintenance**. Partner shall establish, maintain and enforce the Product Trademarks in the Territory and will bear all costs and expenses relating to maintenance of the Product Trademarks, Product Trade Dress and Product-specific website domains.

(c) **Use**. All uses of the Product Trademarks, Product Trade Dress and Product-specific website domain names by Partner (and its Affiliates, Approved Sublicensees, and Distributors) to identify and/or in connection with the Commercialization of the Product in the Field in the Territory shall be in accordance with Regulatory Approvals and all applicable Laws. Partner (and its Affiliates and any Approved Sublicensees and Distributors) shall use the Product Trademarks and Product Trade Dress solely pursuant to the terms of this Agreement to identify and in connection with the Commercialization of the Product in the Territory for use in the Field, and Partner shall not (and shall cause its Affiliates, Approved Sublicensees, and Distributors not to) use such Product Trademarks or Product Trade Dress to identify or in connection with the marketing of any other products.

7.7 **Compliance.**

Each Party shall, to the extent they are responsible for activities in connection with Developing, Manufacturing, seeking Regulatory Approval and/or Commercializing the Product in the Territory, comply with all applicable Laws, including the Anti-Corruption Laws, as well as all applicable Regulatory Approvals for the Product. In addition, each Party shall, to the extent they are responsible for activities in connection with Development or Commercialization of the Product hereunder, not use in any capacity any Person who has been debarred pursuant to Article 306 of the Federal Food, Drug and Cosmetic Act (or similar Law outside of the U.S.), or who is the subject of a conviction described in such Article, and each Party shall inform the other in writing immediately if it or any Person who is performing services for such Party hereunder is debarred or is the subject of a conviction described in Article 306 (or similar Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to the debarment of such Party or any Person used in any capacity by such Party in connection with its Development or Commercialization of the Product hereunder. Partner shall not appoint any Sanctioned Person as a wholesaler, distributor or reseller for the Product, or make any other such appointment that would otherwise be in violation of applicable Laws or cause Atara to be in violation of any applicable Laws.

7.8 **Cell Selection.**

During the R&D Pre-Transfer Period, Atara shall provide to Partner and its Affiliates and their Approved Sublicensees Cell Selection services for the Product in the Field for Commercialization (a) in the Initial Territory, [***], and (b) in the Additional Territory, [***].

The responsibility for Cell Selection in relation to Product in the Field and in the Territory (including the Initial Territory and the Additional Territory) will be transferred from Atara to Partner, such Affiliate or such Approved Sublicensee no later than [***]. Notwithstanding the foregoing, Atara will provide, at any time within [***] after Partner's written request therefor, the right for Partner to assume sole responsibility for the Cell Selection services for the Product in the Field throughout the Territory, or as otherwise mutually agreed between the Parties. Partner and such Affiliate shall use, and shall cause its Approved Sublicensee, if applicable, to use, Commercially Reasonable Efforts to successfully transfer and enable the successful performance of such Cell Selection activities by Partner, such Affiliate or such Approved Sublicensee. Following such transfer, Partner shall, and shall cause such Affiliate or Approved Sublicensee (as applicable), to conduct Cell Selection as necessary for Partner to Commercialize the Product. For clarity, subject to Section 4.2, in no event shall Atara be required to provide such Cell Selection services to Partner on or after the date of expiration of the R&D Pre-Transfer Period, provided that if such activities have not been transferred in accordance with the Transition Plan and Section 4.2, then Atara shall continue to provide such Cell Selection services to Partner (i) in the Additional Territory, [***], and (ii) in the Initial Territory, [***]. For clarity, the cost charged to Partner for such Cell Selection services shall be Atara's FTE Costs and Out-of-Pocket Costs (including, without limitation, the IT systems costs and expenses) [***].

7.9 **Notification.**

Each Party shall promptly notify the other Party if such Party becomes aware of (a) any information that is likely to have a material adverse effect upon Partner's ability to successfully Commercialize the Product in the Field in the Initial Territory, and (b) any event that has a material adverse effect upon Partner's ability to Commercialize the Product in the Field in the Additional Territory.

7.10 **Order Handling; Order to Cash**

Partner shall be solely responsible, at its sole cost and expense, for order intake and order management, as well as invoicing and cash collection (order-to-cash) for sale of the Product in the Territory.

7.11 **Limitation on [***].**

During the Term, Atara and its Affiliates [***].

7.12 **Limitation on Activities Inside the Field and Territory.**

From the Original Effective Date through the period that is [***] after the Execution Date (the "**Limited Period**"), Atara and its Affiliates shall not, and shall not grant any rights under the Atara Patent Rights to any of their respective licensees and sublicensees to, other than the Development of the Product in the Territory as specifically authorized under this Agreement, develop nor commercialize any product [***]. For the avoidance of doubt, a chimeric antigen receptor T-cell shall not constitute an EBV Restricted Product but shall constitute a Cell Therapy Restricted Product. Following the Limited Period and during the Term, [***]. The provisions of this Section 7.12 shall not apply to any Restricted Product, Restricted Product

candidate, or development program of an acquiror of Atara, including its Affiliates or subsidiaries, in each case, existing as of the date of the acquisition by such acquiror of Atara, [***].

7.13 **Partner Non-Compete.**

During the Limited Period, none of Partner, its Affiliates and the Approved Sublicensees shall directly or indirectly develop or commercialize, or enable any such Affiliate, Approved Sublicensee to develop or commercialize, any Restricted Product, other than Product, for use in the Territory. Following the Limited Period, none of Partner, its Affiliates and the Approved Sublicensees shall directly or indirectly develop or commercialize, or enable any such Affiliate, Approved Sublicensee to develop or commercialize, any Restricted Product, other than Product, for use in any country, region, or jurisdiction in the Territory, as long the Product is the subject of [***]. The provisions of this Section 7.13 shall not apply to any Restricted Product of an acquiror of Partner, including its Affiliates or subsidiaries, in each case, existing as of the date of the acquisition by such acquiror of Partner, [***].

7.14 **Limitation on Pursuit of Generic Product.**

During the Term, none of Partner or its Affiliates, Approved Sublicensees, or Distributors shall practice, or authorize any Third Party to practice, any Atara Intellectual Property for any purpose other than as expressly authorized in this Agreement. Additionally, during the Term, none of Partner or its Affiliates, Approved Sublicensees, or Distributors nor Atara or its Affiliates shall (a) take any action to seek, or engage in, the development, regulatory approval, manufacture or commercialization of a Generic Competitor or (b) enable any Third Party to do the same.

ARTICLE 8
Manufacturing and Supply Matters

8.1 **Manufacturing and Supply Agreement.**

Prior to the Execution Date, the Parties have entered into that certain Original Manufacturing and Supply Agreement, which provides for the Manufacture and supply, by or on behalf of Atara to Partner, of Product in the Field in the Initial Territory. During the R&D Pre-Transfer Period, the Parties will negotiate and execute a new amended and restated manufacturing and supply agreement (the "**Manufacturing and Supply Agreement**" or "**MSA**") for the Manufacture and supply of the Product throughout the Territory (including the Additional Territory) until the Manufacturing Transition Date, [***]. Prior to the Manufacturing Transition Date, Partner shall purchase from Atara or its Affiliates all of Partner's, and its Affiliates' and Approved Sublicensees' requirements of Product in the Field in the Territory pursuant to the terms and conditions of the MSA, provided that until such time as the Parties have executed the MSA, Partner shall purchase from Atara or its Affiliates all of Partner's, and its Affiliates' and Approved Sublicensees' requirements of Product in the Field in the Territory [***].

8.2 **Manufacturing Responsibilities.**

Prior to the Manufacturing Transition Date, Atara shall perform and carry out its

Manufacturing responsibilities set forth in this Agreement and the Original Manufacturing and Supply Agreement or MSA, as applicable. Notwithstanding anything to the contrary in this Agreement or in the Original Manufacturing and Supply Agreement or MSA (as applicable), if Atara requests to perform any of its Manufacturing responsibilities through a facility of an Atara Affiliate or Third Party subcontractor that has not been designated by Atara as an Atara Manufacturing Facility as of the Execution Date, and Partner unreasonably withholds, conditions or delays consent for such facility to be included as an Atara Manufacturing Facility hereunder, then Atara shall not be liable for any inability to perform its obligations under the MSA as a result thereof. Additionally, at Partner's sole cost and expense in accordance with the Transition Budget, Atara shall be responsible for using Commercially Reasonable Efforts to conduct (a) PV3.3-associated comparability testing and process qualification activities associated assay development and drafting of the Process Performance Qualification (PPQ) and Comparability sections to support the PV3.3 Type II variation (EMA) and the Post Approval Supplement (PAS) for the FDA, and (b) (i) process development for PV3.4, (ii) applicable technology transfer of new Product version PV3.4 to Fuji Diosynth Biotechnologies California ("**FDBC**"), (iii) associated comparability testing and process qualification activities, (iv) associated assay development, and (v) drafting of the Process Performance Qualification (PPQ) and Comparability sections to support the PV3.4 Type II variation (EMA) and the Post Approval Supplement (PAS) for the FDA.

8.3 **Quality Agreement.**

Prior to the Execution Date, the Parties have entered into that certain Original Quality Agreement, which covers the manufacturing, primary Packaging, testing, storage, transportation to and within Europe, Cell Selection and other quality-related activities for the Product to be conducted by Parties, respectively. The Parties will negotiate and execute concurrently with the MSA a new amended and restated quality agreement (the "**Quality Agreement**") for the manufacture and supply of the Product throughout the Territory (including the Additional Territory) on mutually agreed terms and conditions that are customary for agreements of this type, including customary audit rights of an Atara Manufacturing Facility.

8.4 **Return of Product.**

All returns of Product shall be in accordance with the Product return protocol specified in the Original Manufacturing and Supply Agreement and the Original Quality Agreement, or the MSA and Quality Agreement, as applicable.

8.5 **Atara Supply Obligation.**

(a) The obligations of Atara under this Article 8, including the obligations to Manufacture (or have Manufactured by an Atara Manufacturing Facility) and supply Product to Partner hereunder, shall continue from the Effective Date until the earlier of [***]. For as long as Atara remains responsible for the Manufacture and supply of Product hereunder, Atara will sell to Partner and Partner shall purchase from Atara (i) all PV3.2AT, PV3.3 and PV3.4 batches of Product, in their entirety, that are Manufactured and Released prior to the Manufacturing Transition Date (to be purchased by Partner on the date of Release) and (ii) all batches of Product, in their entirety, for which Manufacture is in progress on the Manufacturing Transition Date (including, without limitation, any and all such batches that are Released after the Manufacturing

Transition Date), in each case (i) and (ii) with Partner making such purchase on the applicable date of Release for each such batch all [***].

(b) Upon the Manufacturing Transition Date and throughout the remainder of the Term, Partner shall have the sole responsibility for Manufacturing Product, or having Product Manufactured, for use in the Territory. Notwithstanding anything to the contrary in this Agreement or in the Original Manufacturing Agreement or MSA (as applicable), on and after the Manufacturing Transition Date, Partner shall be required to use no less than the same level of diligence efforts in conducting the Manufacture and supply of the Product as required of Atara prior to the Manufacturing Transition Date under the Original Manufacturing and Supply Agreement and the Original Commercialization Agreement. To facilitate the transition of responsibility for Product Manufacturing and supply from Atara to Partner (i) subject to Section 8.5(a), at any time within [***] following Partner's written request to Atara therefor, Atara will provide the right for Partner to assume sole responsibility for the Manufacture and supply of the Product in the Field in all countries of the Territory, in accordance with the Transition Plan, and (ii) on or prior to the Manufacturing Transition Date, Atara shall use Commercially Reasonable Efforts to negotiate with each applicable counterparty to bifurcate any Transferred Contracts for Product Manufacturing and supply arrangements to which Atara or its Affiliate is a party (including, the Transferred Contracts with FDBC and/or CRL), in accordance with Section 4.3. Partner shall bear associated costs in accordance with Section 4.3.

(c) Upon the Manufacturing Transition Date, or earlier, to the extent reasonably practicable, Partner shall seek revision of all Regulatory Approvals related to the Commercialization of the Product in the Territory to reflect Partner or its selected third party manufacturer (the "**Selected Manufacturer**") as the Manufacturer. Following the expiration of the R&D Pre-Transfer Period, Partner shall be responsible, at Partner's sole cost and expense, for all Regulatory Interactions and Regulatory Filings relating to PV3.3 and PV3.4. Atara shall provide Partner, at Partner's sole cost and expense, with reasonable regulatory support to (i) enable Partner to draft any and all required variation applications, (ii) address inquiries from any Regulatory Authorities, and (iii) prepare for PAI inspections from both EMA and FDA, in each case (i) through (iii), as necessary in order to manufacture the Product either at Charles River Laboratories ("**CRL**") or FDBC.

(d) Notwithstanding anything to the contrary in this Agreement or the Original Manufacturing and Supply Agreement or the MSA (as applicable), Partner shall order and purchase from Atara, and Atara will sell to Partner, any and all quantities of PV3.2AT, PV3.3 and PV3.4 supply in full batches (and not by vial). To the extent any terms of the Original Manufacturing and Supply Agreement or MSA (as applicable) conflict with Section 8.5(a) or Section 8.6, Section 8.5(a) and Section 8.6 shall control.

8.6 **Inventory.**

(a) Partner shall acquire and purchase (as applicable) from Atara and Atara shall transfer and sell (as applicable) to Partner all of the finished Product inventory owned and Released by Atara (consisting of finished Product manufactured using PV3.2AB, PV3.2AT, and PV3.3) and in existence as of the Effective Date (the "**First Inventory Purchase**"), in accordance with the terms set forth in Schedule 8.6(a), attached hereto.

(b) Additionally, Partner shall purchase from Atara and Atara shall sell to Partner all Product-Specific Intermediates owned and Released by Atara in existence on the Manufacturing Transition Date (the "**Second Inventory Purchase**"), in accordance with the terms set forth in Schedule 8.6(b), attached hereto.

ARTICLE 9
Intellectual Property Matters

9.1 **Ownership of Intellectual Property.**

The Parties acknowledge that, as between the Parties, (i) Atara Controls the Atara Intellectual Property, and (ii) Partner Controls any Partner Intellectual Property as well as any Development Data generated as of the Effective Date.

9.2 **Prosecution.**

(a) Partner acknowledges that, as between the Parties, Atara, in part through MSK, has the sole right, but not the obligation, at its sole cost and expense, to file, prosecute and maintain the Patent Rights in the Territory constituting Atara Intellectual Property, provided that any newly filed patent application (*i.e.*, a patent application that is not included in the Patent Rights listed on Exhibit C) shall not extend the Royalty Term in any country under this Agreement. Atara shall keep Partner reasonably informed of the progress of its prosecution efforts (including any office actions or inter partes proceedings pertaining to or involving any Atara Patent Rights), by providing Partner with copies of all material patent prosecution documentation so that Partner may be informed and advise Atara on the continuing prosecution, and Atara agrees to consider in good faith all such reasonable comments. Partner shall keep this documentation confidential. If Atara elects not to file, prosecute or maintain a Patent Right in any country in the Territory, then it shall notify Partner in writing at least [***] before any deadline applicable to the filing, prosecution or maintenance of such Patent Right, as the case may be, or any other date by which an action must be taken to establish or preserve such Patent Right in such country or possession. Upon notification, Partner may elect to assume thereafter the costs of the filing, prosecution, or maintenance of such Patent Right. In such event, Atara shall file, prosecute or maintain such Patent Right and Partner shall reimburse such costs directly incurred with respect to the filing, prosecution, or maintenance of such Patent Right upon receipt of the corresponding invoice from Atara.

(b) Atara acknowledges that, as between the Parties, Partner has the sole right, but not the obligation, at its sole cost and expense, to file, prosecute and maintain the Patent Rights in the Territory constituting Partner Intellectual Property as well as Patent Rights covering Development Data generated as of the Effective Date. Partner shall keep Atara reasonably informed of the progress of its prosecution efforts (including any office actions or inter partes proceedings pertaining to or involving any Patent Rights constituting Partner Intellectual Property), by providing Atara with copies of all material patent prosecution documentation so that Atara may be informed and advise Partner on the continuing prosecution. Atara shall keep this documentation confidential.

9.3 **Enforcement in the Territory.**

(a) Each Party shall promptly notify the other Party in writing of any existing or threatened infringement, unauthorized use or misappropriation of the Atara Patent Rights in the Territory by reason of the Manufacture, use or sale of a product identical to or substantially similar to the Product (each, a "**Competitive Infringement**") and shall provide all evidence in such Party's possession demonstrating such infringement.

(b) Subject to Section 9.3(c) hereto and MSK's rights under the MSK Agreement, as between the Parties, Partner shall have the first right, but not the obligation, at its sole cost and expense, to initiate an infringement action or other appropriate suit to enforce the Product Patent Rights in the Territory against any Competitive Infringement (each such action, a "**Competitive Infringement Action**"). Atara shall provide to Partner reasonable assistance in such enforcement, at Partner's request, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. Partner shall keep Atara regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider Atara's comments on any such efforts. Atara shall be entitled to separate representation in any such matter by counsel of its own choice and at its own expense, but Atara shall at all times cooperate fully with Partner in bringing such action.

(c) If Partner, in its sole discretion, determines not to exercise its right to bring any Competitive Infringement Action against a Competitive Infringement of the Product Patent Rights in the Territory, then Atara shall be entitled to bring such Competitive Infringement Action at its sole cost and expense.

(d) Subject to Section 9.3(e) hereto, Partner acknowledges that, as between the Parties, Atara has (i) the first right, but not the obligation, at its sole cost and expense, to enforce the Atara Patent Rights (other than the Product Patent Rights) in the Territory against any Competitive Infringement, and (ii) the sole right, but not the obligation, at its sole cost and expense to enforce any the Atara Patent Rights (including the Product Patent Rights) in the Territory against any other Third Party infringement, unauthorized use, misappropriation or threatened infringement thereof. Partner shall provide to Atara reasonable assistance in any enforcement of the Atara Patent Rights in the Territory against any Third Party infringement, at Atara's request, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. Atara shall keep Partner regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider Partner's comments on any such enforcement efforts. Partner shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but Partner shall at all times cooperate fully with Atara in bringing such action.

(e) If Atara, in its sole discretion, determines not to exercise its first right to bring a Competitive Infringement Action against any Competitive Infringement of the Atara Patent Rights (other than the Product Patent Rights) in the Territory, subject to Memorial Sloan Kettering Cancer Center's secondary right to bring a Competitive Infringement Action against such Competitive Infringement of the Atara Patent Rights in the Territory as detailed in the MSK Agreement, Partner shall be entitled to bring such a Competitive Infringement Action at its sole cost and expense.

(f) A Party with responsibility for enforcement against a Competitive Infringement under this Section 9.3 hereto shall not settle any Competitive Infringement Action

that it brought under this Section 9.3 involving Atara Patent Rights without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided that the other Party shall have the sole discretion to withhold consent in the event that such settlement would (i) restrict in any material respect the scope of the Atara Patent Rights or its rights or interests therein or otherwise adversely impact the Atara Patent Rights, or (ii) adversely impact the Development, Commercialization, any Regulatory Approval or any Regulatory Exclusivity of the Product in the Territory.

(g) If either Party recovers monetary damages from any Third Party in a Competitive Infringement Action brought hereunder with respect to the Atara Patent Rights, including in a settlement, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), [***].

9.4 **Infringement of Third Party Patent Rights.**

If a Party becomes the subject of a Third Party's claim or assertion of infringement of a Third Party Patent Right granted by a jurisdiction within the Territory with respect to the Commercialization of the Product in the Field in the Territory, or the Cell Selection, Development or Manufacture of the Product in the Field for Commercialization in the Field in the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, and thereafter, the Parties shall promptly meet to consider the claim or assertion and mutually agree upon the appropriate course of action, but each of them shall be entitled to defend itself provided that it shall keep the other Party regularly informed of the status and progress of such defense efforts, shall reasonably consider the other Party's comments, and shall not settle any claim, suit or action without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided that the other Party shall have the sole discretion to withhold consent in the event that such settlement would impose any obligation or liability on the other Party.

9.5 **Patent Marking.**

Partner shall mark Product marketed and sold by Partner (or its Affiliate and their Approved Sublicensees) hereunder with appropriate patent numbers or indicia, where relevant.

ARTICLE 10
Payments

10.1 **Upfront Payments.**

Pursuant to the Original Commercialization Agreement, prior to the Effective Date, Partner paid to Atara an upfront fee of Forty-Five Million Dollars ($45,000,000) in partial consideration for the licenses granted under the Original Commercialization Agreement (the "**Initial Upfront Payment**"). No later than ten (10) Business Days after the Effective Date, Partner shall pay to Atara an additional upfront fee of Twenty Million Dollars ($20,000,000) in partial consideration for the additional licenses granted hereunder (the "**Additional Upfront Payment**"; and together with the Initial Upfront Payment, the "**Upfront Payments**"). The Upfront

Payments shall be non-refundable, non-recoupable and non-creditable against any other amounts payable hereunder.

10.2 **Development Milestones.**

Partner shall make the following one-time milestone payments to Atara for the milestone events set forth in this Section 10.2:

(a) Centralized Marketing Authorization in the European Union of the Product for EBV+ PTLD in the solid organ transplant (SOT) and hematopoietic cell transplant (HCT) settings: Ten Million Dollars ($10,000,000). The Parties acknowledge and agree that, pursuant to the Original Commercialization Agreement and prior to the Execution Date, Partner has paid to Atara the milestone payment set forth in this Section 10.2(a).

(b) Following grant of Centralized Marketing Authorization in the European Union of the Product for EBV+ PTLD in the solid organ transplant (SOT) and hematopoietic cell transplant (HCT) settings, Atara's filing of an application for transfer of the associated Marketing Authorization to Partner: Thirty Million Dollars ($30,000,000). The Parties acknowledge and agree that, pursuant to the Original Commercialization Agreement and prior to the Execution Date, Partner has paid to Atara the milestone payment set forth in this Section 10.2(b).

[***].

.

10.3 **Commercial Milestones.**

Partner shall make the following one-time milestone payments to Atara for the milestone events set forth in this Section 10.3:

[***].

10.4 **Royalties on Net Sales.**

(a) **Royalties in the Initial Territory**. From the Original Effective Date and through the end of the Royalty Term, on a country-by-country basis solely with respect to the Royalty Term, Partner shall make the following royalty payments to Atara on Net Sales of Product in the Initial Territory at a rate of:

[***].

(b) **Royalties in the Additional Territory**. From the Effective Date and through the end of the Royalty Term, on a country-by-country basis solely with respect to the Royalty Term, Partner shall make the following royalty payments to Atara on Net Sales of Product in the Additional Territory at a rate of:

[***].

10.5 **Third Party Licenses.**

In the event that Partner determines in its good faith judgment with advice from independent legal counsel that it is necessary to obtain a license to any Third Party Patent Rights in the Territory, wherein Partner's Commercialization of the Product in the Field in the Territory would infringe such Third Party Patent Rights absent a license thereunder, and Partner obtains a license under such Patent Rights, Partner may deduct from the amounts due to Atara during the applicable Royalty Term under Section 10.4(a) or Section 10.4(b) an amount equal to [***] of any royalty payments on net sales actually paid to any such Third Party as consideration solely for any such license to such Patent Rights in the Territory; provided, however, that in no event shall the royalties owed to Atara under Section 10.4(a) and Section 10.4(b) be reduced, in the aggregate, by more than [***]. Partner agrees to provide Atara a true, complete and unredacted copy of any license or other agreement subject to this Section 10.5 within [***] of entering into such license agreement.

10.6 **Generic Competitor.**

If during the Royalty Term, a Third Party Generic Competitor receives Regulatory Approval, enters the market for sale in the Initial Territory or the Additional Territory, respectively, and (i) achieves a Generic Market Share of at least [***] in any particular Calendar Quarter in any country(ies) of the Initial Territory or the Additional Territory, as applicable, then in lieu of the royalty rates specified in Section 10.4(a) and (b) hereto, the royalty rate applicable to Net Sales of Product by Partner, its Affiliates, and Approved Sublicensees in such country(ies) in that Calendar Quarter shall be [***] or (ii) achieves a Generic Market Share of greater than [***] in any particular Calendar Quarter in any country(ies) in the Initial Terriotry or the Additional Territory, as applicable, then in lieu of the royalty rates specified in Section 10.4(a) and (b) hereto, the royalty rate applicable to Net Sales of Product by Partner, its Affiliates, and Approved Sublicensees in such county(ies) in that Calendar Quarter shall be [***].

10.7 **Academic Hospital Manufacturer.**

If during the Royalty Term, on a country-by-country basis in the Initial Territory or the Additional Territory, respectively, a product meeting the requirements of clause (a) and (b) of the defined term "Generic Competitor" is manufactured and sold by an academic hospital in a country in the Territory, Partner shall provide written notice to Atara of the sales of such product in such country and if the Parties mutually agree that the impact of such sales by the academic hospital is material, [***].

10.8 **Milestone Reports and Payments.**

(a) Atara shall notify Partner (or Partner shall notify Atara, as applicable) in writing within [***] after Atara or Partner first learns of the achievement of each milestone set out in Section 10.2. The corresponding milestone payment by Partner shall be due to Atara within [***] of receipt by Partner of an invoice from Atara and issued no earlier than the notice of achievement of the corresponding milestone event.

(b) Partner shall notify Atara in writing within [***] after Partner first learns of

the achievement of each milestone set out in Section 10.3. The corresponding milestone payment by Partner shall be due to Atara within [***] of receipt by Partner of an invoice from Atara and issued no earlier than the notice of achievement of the corresponding milestone event.

(c) All payments due under Sections 10.2, 10.3 and 10.8 shall be payable, in full, in U.S. dollars, and shall be made by wire transfer to the Atara bank account specified in Exhibit D attached hereto, or to such other bank account designated in writing by Atara at least [***] prior to the applicable payment date, which account shall be opened in Atara's name in the book of a bank in the European Union or the United States of America. Atara agrees to provide to Partner all information and documents required by Partner in connection with the relevant provisions of Laws relating to anti-money laundering/KYC and which are sufficient to allow Partner to comply with such Laws.

(d) Any milestone made by Partner to Atara pursuant to Article 10 hereto shall be non-refundable, non-creditable, and non-cancellable.

10.9 **Royalty Reports and Payments.**

(a) **Reports**. Within [***] after the end of each Calendar Quarter, commencing with the Calendar Quarter in which occurs the first invoiceable sale of Product in the Field in the Territory for which royalties are due and payable by Partner, its Affiliates or their Approved Sublicensees, Partner shall deliver to Atara a report (each, a "**Royalty Report**") setting out in compliance with the template attached in Exhibit F all details necessary to calculate the payments due under Section 10.4, including royalty bearing Net Sales and the number of units sold in the relevant Calendar Quarter on a country-by-country basis, all relevant exchange rate conversions in accordance with Section 10.8(b) and the amount of any payment due from Partner to Atara, calculated in accordance with this Article 10. [***]. The royalty payment shall be due within [***] date of invoice and issued no earlier than the date of receipt of the Royalty Report by Atara.

(b) **Payments**. All payments due under Sections 10.4 and 10.9 of this Agreement shall be payable, in full, in U.S. dollars, regardless of the country(ies) in which Net Sales are made. For the purposes of computing Net Sales of Products sold in a currency other than U.S. dollars, such currency shall be converted into U.S. dollars using the average quarter to date rate of exchange as consistently applied per Partner's internal accounting and reporting process. Such payments shall be without deduction of exchange, collection or other charges. All payments owed under this Agreement shall be made by wire transfer to the Atara bank account specified in Exhibit D attached hereto, or to such other bank account designated in writing by Atara at least [***] prior to the applicable payment date, which account shall be opened in Atara's name in the book of a bank in the European Union or the United States of America. Atara agrees to provide to Partner all information and documents required by Partner in connection with the relevant Laws relating to anti-money laundering/KYC policies which are sufficient to allow Partner to comply with such Laws.

(c) **Record Retention**. Beginning with the first invoiceable sale of a Product in the Field in the Territory, Partner shall keep complete and accurate records pertaining to the sale of such Products including the original data files used to prepare the submitted Royalty Reports,

for a period of [***] after the year in which such sales occurred, and in sufficient detail to permit Atara to confirm the accuracy of the royalties paid by Partner hereunder.

(d) **Late Payments**. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest daily from the date due at the rate of [***]; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Atara from exercising any other rights it may have as a consequence of the lateness of any payment.

10.10 **Audits.** During the Term of this Agreement and for a period of [***] thereafter, at the request and expense [***], Partner shall permit an independent, certified public accountant of nationally recognized standing appointed by Atara, and reasonably acceptable to Partner, at reasonable times and upon reasonable notice, but in no case no more than once for any particular royalty period, or more than [***] thereafter, to examine such records as may be necessary for the sole purpose of verifying the calculation and reporting of Net Sales and the correctness of any royalty payment made under this Agreement for any period within the preceding [***]. Results of any such examination shall be made available to both Partner and Atara. The independent, certified public accountant shall disclose to Atara only the royalty amounts which the independent auditor believes to be due and payable hereunder to Atara and shall disclose no other information revealed in such audit. Any and all records examined by such independent accountant shall be deemed Partner's Confidential Information which may not be disclosed by said independent, certified public accountant to any Third Party. Notwithstanding the above, if such audit reveals an underpayment by Partner in excess of [***] of the total payments made during the audited period, or [***] during any [***] period, then Partner shall pay the reasonable costs of the auditors plus interest on the discrepancy as provided for late payments under Section 10.9(d) within [***] of the completion of the applicable audit.

10.11 **Reimbursement for Transition Costs.**

(a) Partner shall reimburse Atara for the Transition Costs identified in the Transition Plan as being the Partner's responsibility and reimbursable by Partner, including when and as provided any and all Transition Costs accounted for in the Transition Budget in accordance with this Section 10.11.

(b) Within [***] after the end of each [***], Atara shall provide to Partner a report of its actual Transition Costs incurred under the Transition Plan for such [***](each, a "**Financial Report**"), in such format as set forth in Schedule 10.11(b) as Atara shall establish for use in accordance with its Accounting Standards. Each Financial Report shall specify in reasonable detail, as applicable, the Transition Costs in the corresponding [***] incurred by Atara in accordance with this Agreement in such [***] and shall include an accounting of FTE Costs and Out-of-Pocket Costs incurred by Atara for such [***] for each Transition Plan. For the avoidance of doubt, Out-of-Pocket Costs may include, without limitation, certain (i) reasonable allocations of invoices received that are not solely related to the Product (*e.g.*, lab supplies), and (ii) accruals that are based on Atara's Accounting Standards (*e.g.*, clinical trial progress).

(c) **Audit Rights**. Once per [***] until the completion of the Transition Plan and no later than [***] following the date of completion of the Transition Plan, at the request and

expense of [***], Atara shall permit an independent Third Party accountant appointed by Partner and reasonably acceptable to Atara, at reasonable times and upon reasonable notice, to examine such records as may be necessary for the sole purpose of verifying the calculation and reporting of Atara's Out-Of-Pocket Costs for any [***]. Results of any such examination shall be made available to both Partner and Atara. Notwithstanding the above, if such audit reveals an overstatement by Atara of all of its Out-of-Pocket Costs for the Calendar Year in excess of [***] then Atara shall pay the reasonable costs of the auditors plus interest on the discrepancy as provided for late payments under Section 10.9(d) within [***] of the completion of the applicable audit. Partner shall not conduct an audit for the same [***] more than once.

(d) **Forecasting and Overruns.**

(i) Atara shall provide an updated Transition Budget once per [***] in accordance with its annual budgeting process prior to [***], together with a forecasted budget in reasonable detail of the Transition Costs to be incurred in connection with its activities under the Transition Plan until the completion of the Transition Plan.

(ii) Atara shall notify Partner without undue delay upon becoming aware that the anticipated Transition Costs to be incurred by Atara for a given [***] are projected to be in excess of the approved Transition Budget for such [***] by [***] or more (such amount in excess being referred to as the "**Excess Costs**").

(iii) The Parties shall discuss the causes of any such increase and evaluate potential mitigation measures to prevent a further increase of Transition Costs.

(iv) Excess Costs shall not be included in the calculation of the applicable Transition Costs and shall not be reimbursable by Partner except with Partner's consent, provided that Partner shall not unreasonably withhold, condition or delay any such consent if such Excess Costs are due to circumstances not attributable to Atara and Atara has used Commercially Reasonable Efforts to mitigate a further increase of Transition Costs.

(v) For clarity, upon any consent of Partner to include Excess Costs in the Transition Costs for any given [***], the Transition Budget for such [***] will be increased upon such consent of Partner to account for such Excess Costs, and such Excess Costs will be included in the calculation of the applicable Transition Costs (and reimbursable by Partner) for such [***].

(vi) Notwithstanding anything to the contrary herein, if (A) Excess Costs in a particular [***] are a result of, or otherwise attributable to, under spend in a prior [***] or acceleration of spend expected in a future [***], and (B) the overall Transition Budget remains unchanged, then such Excess Costs shall be included in the calculation of the Transition Costs and reimbursable by Partner.

(e) **No Double Counting**. For the avoidance of doubt, no cost or expense will be counted more than once in calculating Transition Costs even if such cost or expense falls into more than one of the cost categories included in Transition Costs.

(f) **Reimbursement Payments.** Subject to other provisions of this Section 10.11, Partner shall make the associated reimbursement payment of Transition Costs within [***] of the date of invoice. All reimbursement payments owed under this Section 10.11 shall be made by wire transfer to the Atara bank account specified in Exhibit D attached hereto, or to such other bank account designated in writing by Atara at least [***] prior to the applicable payment date, which account shall be opened in Atara's name in the book of a bank in the European Union or the United States of America. Atara agrees to provide to Partner all information and documents required by Partner in connection with the relevant Laws relating to anti-money laundering/KYC policies which are sufficient to allow Partner to comply with such Laws.

10.12 **Taxes.**

(a) **Sales or Other Transfers**. The recipient of any transfer under this Agreement of Product or Know-How, as the case may be, shall be responsible for any sales, use, value added, excise or other taxes applicable to such transfer as required by law.

(b) **Withholding**. If Laws or regulations require withholding by Partner of any taxes imposed upon Atara on account of any royalties or other payments paid under this Agreement, such taxes shall be deducted by Partner as required by Law from such payment and shall be paid by Partner to the proper taxing authorities. Partner shall use Commercially Reasonable Efforts to secure official receipts of payment of any withholding tax and shall send them to Atara as evidence of such payment. The Parties shall exercise their reasonable efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of any applicable tax treaty and shall cooperate in filing any forms required for such reduction. Each Party shall cooperate with the other and furnish the other Party with appropriate documents, including Tax Documentation, to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

ARTICLE 11
Representations and Warranties; Disclaimer

11.1 **No Representation of Success.**

Atara does not warrant that Atara can successfully Develop or obtain Regulatory Approvals for the Product in the Field in the Territory.

11.2 **Representations and Warranties of Atara.**

Atara provides to Partner the respresentations and warranties set forth in this Section 11.2 as of the Execution Date and the HSR Clearance Date:

(a) Atara is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent Atara from performing its obligations under this Agreement;

(b) Atara has full right and authority to grant the licenses to Partner as described herein;

(c) The Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Atara enforceable against Atara in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Laws affecting creditors' rights generally from time to time if effect, and to general principles of equity;

(d) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Atara is a party, or by which it is bound, nor does it violate any Law applicable to Atara;

(e) All necessary consents, approvals and authorizations of all regulatory and Governmental Authorities and other persons or entities required to be obtained by Atara in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained;

(f) The Patent Rights within the Atara Intellectual Property listed on Exhibit C constitute a true, accurate and complete list of all Patent Rights within the Atara Intellectual Property in the Territory Controlled by Atara relating to the Products in the Territory;

(g) Atara is the sole and exclusive owner or exclusive licensee (subject to Section 2.1(b) and to routine commercial licenses, and provided that certain Know-How licensed to Atara by MSK under the MSK Agreement is licensed to Atara on a non-exclusive basis) of all of Atara Intellectual Property in the Territory with respect to Product, including all Patents Rights listed on Exhibit C and Product Trademarks listed on Exhibit E, free from encumbrances, and has the right to grant to Partner the rights granted herein with the respect to the Atara Intellectual Property;

(h) To Atara's knowledge, all individuals who participated in the invention of any of the inventions claimed in the Patent Rights within the Atara Intellectual Property have made effective assignments of all ownership rights either pursuant to written agreement or by operation of applicable Law;

(i) To Atara's knowledge, all application and registration fees in respect of the Patent Rights within the Atara Intellectual Property listed on Exhibit C have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of registering such Patent Rights within the Atara Intellectual Property;

(j) All application and registration fees in respect of the Product Trademarks listed on Exhibit E have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of registering such Product Trademarks;

(k) To Atara's knowledge, Atara has not misappropriated any know-how relating to the Development, registration or Manufacturing of the Product, or the conduct of Cell Selection;

(l) There are no actual, pending, alleged, or to Atara's knowledge, threatened actions, suits or claims alleging the misappropriation of any know-how relating to the Development, registration or Manufacturing of the Product, or the conduct of Cell Selection. Atara has taken reasonable precautions to preserve the confidentiality of the Atara Know-How within the Atara Intellectual Property;

(m) Atara has not granted any licenses to any Affiliate or Third Party under the Atara Intellectual Property or Regulatory Approvals to be obtained by Atara hereunder which would conflict with the licenses granted to Partner hereunder;

(n) Atara and its Affiliates have not granted any rights under the Atara Intellectual Property to any of their respective licensees and sublicensees to Develop, conduct Cell Selection, and/or Commercialize the Product in the Territory for use in therapeutic indications outside the Field;

(o) There are no actual, pending, alleged or to Atara's knowledge, threatened action, suits, claims, interference or governmental investigations involving a Product (including with respect to the Development or Manufacturing of a Product or any Regulatory Approval or MAA related thereto) or any Commercialization of a Product, or the conduct of Cell Selection or the Atara Intellectual Property, by or against Atara, or any of its Affiliates, and to Atara's knowledge, no circumstances that may give rise to any such action, suits, claims or investigation;

(p) Atara has not brought a claim alleging an infringement by a Third Party of any of the Atara Intellectual Property. To Atara's knowledge, no Third Party infringes or misappropriates any of the Atara Intellectual Property;

(q) To Atara's knowledge, none of the issued Patent Rights within the Atara Intellectual Property are invalid or unenforceable;

(r) Atara has disclosed to Partner in writing copies of: (i) any and all material study reports, or synopses of the materials aspects thereof, from Clinical Studies or GLP preclinical studies of the Product in its possession, and (ii) all material filings and correspondence between Atara and its Affiliates and the EMA and FDA, relating to clinical or preclinical studies of the Products, and such information and materials are true and accurate in all material respects;

(s) No information or materials provided by or on behalf of Atara to Partner including in the data room, when taken together as a whole, contain any untrue or misleading statement of a material fact or, to Atara's knowledge, omit to state a material fact, in each case, that is likely to have a material adverse impact, on the Regulatory Approvals, Manufacturing and/or Commercialization, in each case, for the Product in the Territory, or the conduct of Cell Selection. In particular, (i) Atara has disclosed all Material Contracts to Partner and (ii) the MSK Agreement as well as the Transferred Contracts represent all Material Contracts;

(t) All data with respect to the Product that (i) is intended to be or was provided to a Regulatory Authority, or (ii) was provided by Atara to Partner, was generated in compliance with applicable Laws in all material respects;

(u) In the course of the Development of Product, Atara has not used any employee or consultant who has been debarred by any Regulatory Authority or was the subject of debarment proceedings by a Regulatory Authority, and to Atara's knowledge, no such employees or consultants have been used by any Third Party on behalf of Atara in connection with the Development of the Product. All studies conducted by or on behalf of Atara with respect to the Product have been conducted in accordance with applicable Laws by persons with appropriate education, knowledge and experience in all material respects;

(v) The Existing Agreements are in full force and effect in accordance to their terms as disclosed to Atara. No terms of the Existing Agreements material to the rights granted to Partner hereunder have been redacted in the Existing Agreements made available to Partner;

(w) No Third Party has any right of consent, right of first negotiation or similar rights under the Existing Agreements, that could materially interfere with Partner's exercise of its sublicensing rights under this Agreement;

(x) Atara has maintained in full force and effect all material agreements (including the Existing Agreements in accordance with its terms) and filings (including Patent Rights filings) necessary to perform its obligations hereunder. Atara and its Affiliates are in compliance with the Existing Agreements and have performed all material obligations required to be performed by them to date under the Existing Agreements. Neither Atara nor its Affiliates are (with or without the lapse of time or the giving of notice, or both) in material breach in any respect under the Existing Agreements;

(y) Atara has no knowledge of any breach of the representations and warranties given by the parties to Existing Agreements;

(z) All activities conducted by Atara with respect to the Product have been conducted, in all material respects, in accordance with applicable Laws;

(aa) The First Inventory Purchase has been manufactured in accordance with applicable Regulatory Approvals, GMP and other applicable Laws; and the remaining shelf life of the finished Product inventory owned by Atara as of the Execution Date, is set forth in Schedule 11.2 hereto; and

(bb) Atara is not (i) aware of any breach by Partner of the Original Commercialization Agreement or any of the Original Ancillary Agreements or (ii) aware of any facts that could form the basis of such a breach of said agreements.

11.3 **Representations and Warranties of Partner.**

Partner covenants, and represents and warrants to Atara that as of the Execution Date and the Effective Date:

(a) Partner is a corporation duly organized, validly existing and in good standing under the laws of jurisdiction in which it is incorporated and it has full right and authority to enter into this Agreement and to accept the rights and licenses granted as herein described;

(b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Partner enforceable against Partner in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Laws affecting creditors' rights generally from time to time if effect, and to general principles of equity;

(c) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Partner is a party, or by which it is bound, nor does it violate any Law applicable to Partner

(d) All necessary consents, approvals and authorizations of all regulatory and Governmental authorities and other persons or entities required to be obtained by Partner in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; and

(e) Partner is not (i) aware of any breach by Atara of the Original Commercialization Agreement or any of the Original Ancillary Agreements or (ii) aware of any facts that could form the basis of such a breach of said agreements.

11.4 **Representations of Both Parties.**

Partner, with respect to itself and its Affiliates that have been or will be involved in the Development, Regulatory Filing activities and/or Commercialization of the Product in the Territory represents, warrants to Atara that, as of the Execution Date and the Effective Date, and Atara represents, warrants to Partner that, as of the Execution Date and the Effective Date, to the knowledge of such Parties' compliance department:

(a) neither they or their directors, officers, employees, or any person authorized to act on its behalf have violated any Anti-Corruption Law in the Territory;

(b) neither they nor any person acting on its behalf, has offered, given, authorized, or promised anything of value (as defined by applicable Anti-Corruption Laws), either directly or indirectly, to any person, including to any Public Official or Entity, for the purpose of (i) improperly influencing any official act or decision; (ii) inducing performance or non-performance of any act in violation of a lawful duty; or (iii) securing an improper benefit or business advantage, in each case ((i) – (iii)) in any manner that violates the applicable Anti-Corruption Laws in the Territory;

(c) they have not received any written notice, request, or citation from any Governmental Authority with respect to any alleged or suspected violation of Anti-Corruption Laws in the Territory; and

(d) they are not under investigation or being prosecuted by a Government Authority with respect to any alleged or suspected violation of Anti-Corruption Laws in the Territory.

11.5 **Certain Rights and Obligations of Atara.**

(a) Atara shall not during the term of this Agreement (i) grant any lien, pledge, encumbrance, mortgage, or security interest (excluding any license rights or equivalents thereof) (collectively "**Liens**") with respect to this Agreement or any of the Patents Rights within the Atara Intellectual Property in the Territory or (ii) permit such a Lien, to attach to this Agreement or any of such rights, in each case if such Lien would conflict with the rights granted to Partner hereunder.

(b) Upon termination of the MSK Agreement, for the benefit of Partner and should Partner so elect, Atara shall assign to MSK the portion of the Agreement that relates to the MSK Agreement and shall use Commercially Reasonable Efforts to pursue enforcement of Section 17.5 of the MSK Agreement.

(c) Except as set forth in Schedule 1.199, to the extent relating to the Product in the Territory, Atara shall not agree or consent to any substantive amendment, supplement or other modification to the MSK Agreement or the Transferred Contracts (only until the respective Assignment Dates thereof) or exercise any other right of agreement or consent thereunder, in each case to the extent that such amendment, supplement, modification, exercise or consent could materially and adversely affect Partner's rights under this Agreement. Notwithstanding the preceding sentence, Atara shall have the right to do any of the foregoing with Partner's prior consent in writing to the same, which consent shall not be unreasonably withheld, conditioned or delayed (and which agreement or consent of Partner shall be provided within [***] after a request therefor if such amendment, supplement or other modification would not materially and adversely affect Partner's rights under this Agreement).

(d) Except as set forth in Schedule 1.199, Atara shall maintain and keep in full force and effect the MSK Agreement and Transferred Contracts (only until the respective Assignment Dates thereof) in accordance with the respective terms thereof, solely, in each case, with respect to the Product. Notwithstanding the preceding sentence, Atara shall have the right to cease maintaining and keeping in full force and effect the Transferred Contracts with the prior written consent of Partner, which consent shall not be unreasonably withheld, conditioned or delayed.

(e) Atara shall at all times comply in all material respects with the terms of the MSK Agreement and Transferred Contracts (only until the respective Assignment Dates). Atara shall promptly notify Partner of any actual or threatened breach of the MSK Agreement or the Transferred Contracts (only until the respective Assignment Dates) of which Atara becomes aware. Without limiting the foregoing, within [***] after Atara's receipt of any written notice relating to any alleged breach by Atara under such agreements, Atara shall notify Partner thereof, specifying the basis for the alleged breach, as set out in the notice or otherwise known to Atara. Without prejudice to any of Partner's other rights under the Agreement or other remedies available to it, Partner shall have the right to take step to cure an actual payment breach by Atara under any of the MSK Agreement or the Transferred Contracts (only until the respective Assignment Dates) to prevent a termination of such agreement, as applicable. Partner may set off any reasonable and undisputed payments made by or on behalf of Partner in connection with the performance of such steps against any amounts payable by Partner to Atara under this Agreement.

(f) From the Execution Date until the Effective Date, Atara shall:

(i) not take any action or omit to take any action that would result in any of the representations and warranties set forth in Section 11.2 being untrue on the Effective Date, provided that the foregoing shall not restrict Atara from entering into Material Contracts in accordance with the provisions of Schedule 1.199;

(ii) conduct its activities with respect to the Product in the ordinary course of business and shall not cease any material activity with respect to the Development or Manufacturing of the Product.

11.6 **Certain Rights and Obligations of Partner.**

(a) Partner's, and Partner's Affiliates, employees, officers, contractors, and consultants performing activities in connection with this Agreement shall execute or have executed agreements requiring assignment to Partner or Partner's Affiliate, as applicable, all right, title and interest in and to their inventions and discoveries invented or otherwise discovered or generated during the course of and as a result of such activities, whether or not patentable, if any, prior to commencing such activities;

(b) Partner currently has, and will maintain during the Term of this Agreement, directly or through its Affiliates, Approved Sublicensees, and Distributors (i) sufficient qualified and trained personnel and resources, and (ii) necessary financial and technical capacity to effectively fulfill its obligations related to the Product as contemplated in this Agreement.

11.7 **No Other Warranties.**

EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 11, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF PARTNER OR ATARA; (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT; AND (C) ALL KNOW-HOW, INFORMATION AND MATERIALS PROVIDED BY EITHER PARTY TO THE OTHER PARTY UNDER THIS AGREEMENT ARE PROVIDED "AS-IS."

ARTICLE 12
Indemnification; Insurance; Disclaimer

12.1 **Indemnification by Atara.**

Subject to Section 12.3, Atara shall indemnify, defend and hold harmless Partner and its Affiliates, their subcontractors and Approved Sublicensees and its and their shareholders, directors, officers, employees, agents and representatives and insurers (the "**Partner Indemnified Persons**") from and against all Claims that may arise directly or indirectly as a result of: (a) the fraud, gross negligence or willful or wrongful acts or omissions of Atara; (b) a breach by Atara of

any of its representations or warranties under this Agreement; (c) the failure of Atara to comply with applicable Laws; or (d) Atara's Development and associated regulatory activities prior to and under this Agreement (including any such activities under the Transition Plan), and Cell Selection services, in each case, except to the extent such Claim arises directly or indirectly (i) as a result of any of the matters for which Partner is providing indemnification pursuant to Section 12.2 or, (ii) with respect to clauses (b), (c) or (d), from activities conducted by Atara or an Atara designee at the request of Partner.

12.2 **Indemnification by Partner.**

Subject to Section 12.3, Partner shall indemnify, defend and hold harmless Atara and its Affiliates and their subcontractors and its and their shareholders, directors, officers, employees, agents and representatives and insurers (the "**Atara Indemnified Persons**") from and against all Claims that may arise directly or indirectly as a result of: (a) the fraud, gross negligence or willful or wrongful acts or omissions of Partner; (b) a breach by Partner of any of its representations or warranties under this Agreement; (c) the failure of Partner to comply with applicable Laws; or (d) Partner's Development and regulatory activities (including any such activities under the Transition Plan), Manufacture (when transferred to Partner pursuant to this Agreement), Cell Selection services (when transferred to Partner pursuant to this Agreement), and Commercialization of the Products by or on behalf of Partner, in each case, except to the extent such Claim arises directly or indirectly as a result of any of the matters for which Atara is providing indemnification pursuant to Section 12.1.

12.3 **Notice of Claim.**

If a Party intends to claim indemnification under this Agreement (the "**Indemnitee**"), it shall promptly notify the other Party (the "**Indemnitor**") in writing of such alleged loss and the Third Party Claim. The Indemnitor shall have the right to control the defense thereof with counsel of its choice as long as such counsel is reasonably acceptable to Indemnitee. Any Indemnitee shall have the right to retain its own counsel at its own expense for any reason in connection with such Third Party Claim, provided, however, that if the Indemnitee shall have reasonably concluded, based upon a written opinion from outside legal counsel, that there is a conflict of interest between the Indemnitor and the Indemnitee in the defense of such action, the Indemnitor shall pay the fees and expenses of one law firm serving as counsel for the Indemnitee in relation to such Third Party Claim. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Third Party Claims covered by this Agreement. The obligations of this Article 12 shall not apply to any settlement of any Third Party Claims if such settlement is affected without the consent of both Parties, which shall not be unreasonably withheld, conditioned or delayed. Each Party will not, without the prior written consent of the other Party, settle such Third Party Claim or consent to the entry of any judgment to the extent that such settlement or judgment: (i) does not release the other Party from all liability with respect to such Third Party Claim, or (ii) likely will materially adversely affect such other Party or cause such other Party to incur any material obligation or liability. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, to the extent prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Section 12.3. It is understood that only Partner and Atara can claim indemnity under this Agreement (on its own

behalf or on behalf of its Indemnitees), and other Indemnitees may not directly claim indemnity hereunder.

12.4 **Insurance.**

Each Party, at its own cost and expense shall, during the Term of this Agreement and for [***] thereafter, carry and keep in force liability insurance covering such risks as are appropriate and in accordance with sound business practice and the Parties' obligations under this Agreement.

12.5 **Limitation of Liability.**

NEITHER PARTY HERETO WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT IN RESPECT OF ANY BREACH OF (1) A PARTY'S OBLIGATIONS UNDER ARTICLE 13 OR (2) INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12 FOR THIRD PARTY CLAIMS. FOR THE AVOIDANCE OF DOUBT, NOTHING IN THIS CLAUSE SHALL LIMIT OR EXCLUDE ANY LIABILITY TO A THIRD PARTY FOR FRAUD BY ANY PARTY.

ARTICLE 13
Confidentiality; Publications; Data Protection

13.1 **Confidential Information.**

The Parties acknowledge that the Confidential Information include valuable trade secrets and is proprietary and the exclusive property of the disclosing Party and its Affiliates. Unless otherwise set forth in an Ancillary Agreement, during the Term and for a period of [***], the receiving Party shall hold the Confidential Information supplied by the disclosing Party hereunder in strict confidence and shall use such Confidential Information solely for the purposes of performing hereunder. Notwithstanding the foregoing, trade secrets shall be treated as Confidential Information for as long as they retain their status as trade secrets. The receiving Party may only disclose Confidential Information to those directors, officers, employees, attorneys, contractors, agents, potential acquiror's, potential sublicensees, bankers, and Affiliates (each a "**Representative**") who have a need to know and who are bound by obligations of confidentiality and non-use with respect to such Confidential Information that are at least as restrictive as those set forth herein. Each of the Parties agrees to: (a) advise their Representatives of the proprietary nature of the Confidential Information and the terms and conditions of this Agreement requiring that the confidentiality of such information be maintained; and (b) use reasonable safeguards to prevent unauthorized use by such Representatives. Each Party shall be responsible for any breach of this Agreement by its respective Representatives.

13.2 **Agreement Confidentiality.**

Neither Party hereto shall disclose the terms of this Agreement to any other person or entity other than such Party's Representatives, or as may otherwise be required by applicable

Laws. In the event a Party reasonably believes it is required by applicable Laws to disclose any terms of this Agreement, prior to any proposed disclosure of any of the terms of this Agreement, such Party shall allow and reasonably assist the other Party in taking any action to lawfully prevent or limit any such disclosure.

13.3 **Exceptions.**

For the purposes of this Agreement, "**Confidential Information**" shall not include:

(a) Confidential Information which is or becomes public knowledge (through no fault of the Parties or their Representatives in violation hereof);

(b) Confidential Information which is lawfully made available to a Party by an independent third party (and such lawful availability can be properly demonstrated);

(c) Confidential Information which is already in a Party's possession at the time of initial receipt from the other Party (and such prior possession can be demonstrated by competent evidence); or

(d) Confidential Information which is independently developed by a Party or its Representatives and such independent development can be demonstrated by competent evidence.

13.4 **Disclosures Required by Applicable Law.**

Either Party may disclose Confidential Information which is required to be disclosed by applicable Laws or order of any Government Authority to be disclosed; provided, however, that the Party so disclosing shall, give the other Party as much prior written notice as reasonably practicable to permit it to seek a protective order or other similar order with respect to the Confidential Information and, thereafter, shall disclose only the minimum Confidential Information required to be disclosed in order to comply, whether or not the other Party seeks or obtains any such protective or other similar order. Notwithstanding the foregoing, information disclosed as set forth in this Section 13.4 shall not be disclosed to any other Third Party without the prior written consent of the disclosing Party.

13.5 **Injunctive Relief.**

Each Party acknowledges and agrees that its breach of the confidentiality and non-use obligations set forth herein may cause irreparable harm to the disclosing Party which would not be fully compensable by payment of money damages alone, and that in the event of such a breach or threatened breach the disclosing Party shall be entitled to seek equitable relief (including, without limitation, injunctive relief), without the necessity of proving actual damages or posting a bond. Such equitable relief shall be in addition to and not in lieu of any other relief available to the disclosing party at law or in equity.

13.6 **Ownership of Confidential Information.**

All Confidential Information which either Party or any of its Representatives shall

obtain or to which either Party or any such Representative shall be given access pursuant to or in connection with this Agreement, shall be and remain the sole property of the disclosing Party, and the receiving Party shall have no rights or interests (except as expressly provided herein) to or in such Confidential Information.

13.7 **Return or Destruction of Confidential Information.**

Immediately upon the expiration or earlier termination of this Agreement, the receiving Party shall, at the other Party's option, return to the disclosing Party, or provide a certificate of one of its Executive Officers as to the destruction of all Confidential Information (including all copies thereof) then in the possession of the receiving Party or any of its Representatives. Each Party may retain one (1) archival copy of such Confidential Information, which Confidential Information shall be subject to the confidentiality obligations set forth in this Article 13.

13.8 **Data Protection.**

Each Party shall comply with their respective obligations under applicable Data Protection Laws. Where one Party discloses personal data to the respective other Party, the disclosing Party is responsible to ensure meeting all conditions that are legally required to allow this disclosure for purposes of this Agreement (including medical and diagnostic research and development purposes). If such disclosure may include transfer of personal data from the European Economic Area (EEA) to a non-adequate country as defined by the General Data Protection Regulation 2016/679 (GDPR) such a transfer will require the prior conclusion of a specific agreement between the Parties, which they expressly accept, providing for the implementation of the most appropriate transfer mechanism in order to comply with the provisions of the GDPR related to export of personal data outside EEA. Additionally, this disclosure may include, e.g., ensuring that respective Data Subjects have given and not withdrawn their consents, or anonymizing or de-identifying the human personal data prior to disclosure.

13.9 **Publications.**

(a) In the R&D Pre-Transfer Period, if either Party (the "**Publishing Party**") wishes to publish any information, data or results regarding the Product in the Field in the Territory obtained from activities authorized under this Agreement, including any Development Data resulting from the Current Studies in any scientific journals or scientific conferences, a manuscript of the proposed publication shall first be sent to the other Party (the "**Receiving Party**") at least [***] in advance of such publication for review. The Publishing Party shall consider in good faith the Receiving Party's comments during this [***] period and unless the Receiving Party informs the Publishing Party in writing during this [***] period that the proposed publication must be delayed in order to protect a patentable invention or changed to avoid disclosure of the Receiving Party's Confidential Information or adjusted (to the extent scientifically reasonable) to avoid any materially adverse impact on the Development or Commercialization of the Product, the Publishing Party shall be free to publish such results. In the event that a delay of the proposed publication is required, the Publishing Party shall withhold such submission for publication for one additional period, up to [***], or such other period as the Parties may mutually agree.

(b) In the R&D Pre-Transfer Period, if a Party intends to present any information, data or results regarding activities relating to the Product in the Field in the Territory, including any Development Data resulting from the Current Studies, at symposia or other meetings of healthcare professionals, or international and/or US or European congresses, conferences or meetings organized by a professional society or organization, the provision of subclause (b) shall apply *mutatis mutandis* to (i) all abstracts that will be submitted for publication, (ii) all draft slide presentations for use in oral presentations, and (iii) all posters that will be presented at such Scientific Meeting, provided that the [***] review period referred to in subclause (b) shall be reduced to [***].

(c) In the R&D Post-Transfer Period and throughout the Term, Partner shall be free to publish or present any information, data or results regarding activities relating to the Product in the Field in the Territory and Atara shall not, except as otherwise authorized elsewhere in this Agreement, including in this Article 13, publish or present any information, data or results regarding activities relating to the Product in the Field in the Territory.

13.10 **Publicity.**

The Parties shall agree on a joint press release in relation to the execution of this Agreement, following the public dissemination of which (i) either Party may make subsequent public disclosure of the contents of such statement, in a manner reasonably consistent with such contents, without the further approval of the other Party, and (ii) each Party shall be entitled to refer publicly to the relationship of the Parties reflected in this Agreement in a manner that is consistent with the joint press release issued by the Parties. All other publicity, press releases and other announcements relating to this Agreement or the transactions contemplated hereby, including any announcement that discloses the existence of this Agreement or any Development or Commercialization activities with respect to the Product in the Field and in the Territory, shall be reviewed in advance by and subject to the approval of both Parties, which approval shall not be unreasonably withheld, conditioned or delayed; except that:

(a) nothing in this Section 13.10 shall prevent a Party from promptly making all disclosures and filings with Government Authorities as may, in its judgement be required or advisable in connection with the execution and delivery of this Agreement or the consummation of and the performance thereof the transactions contemplated hereby, including, without limitation, disclosures required by the rules and regulations of the SEC, other Government Authority, or applicable stock exchange, provided that except where prohibited by applicable Law or exigent circumstances, the receiving Party takes reasonable best efforts to provide the disclosing Party at least [***] prior written notice of such disclosure (and the right to review and comment on the proposed disclosure), and discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose in the receiving Party's legal counsel opinion;

(b) to the extent that this Agreement and one or more of the Ancillary Agreements may need to be filed by Atara with the SEC, Atara shall, prior to making any such filing with the SEC, provide Partner and its counsel with a proposed redacted version of this Agreement (and any other Ancillary Agreement, as applicable) which it intends to file with the SEC and to give due consideration to any comments provided by Partner or its counsel and use reasonable efforts to obtain confidential treatment for such required disclosure;

(c) following the filing of the Agreement or any Ancillary Agreement with the SEC, Atara may describe or refer to portions of the Agreement or any Ancillary Agreement for which confidential treatment is not obtained from the SEC without the prior review or approval of Partner;

(d) Atara may, only as required by the rules and regulations of the SEC or applicable stock exchange, disclose the Net Sales set forth in any Royalty Report in any earnings release, quarterly report or annual report, as the case may be, in each case without the prior review or consent of Partner; and

(e) either Party shall be free, without the consent of the other Party, to continue to publicly disclose materials previously approved by the other Party to the extent such materials are substantially in the same form as previously approved.

ARTICLE 14
Subcontracting

14.1 **Atara.**

Subject to the terms and conditions of this Agreement, including, without limitation, Section 14.3 hereto, Atara shall have the right to carry out all or any part of its obligations under this Agreement or any Ancillary Agreement through its subsidiaries, Affiliates or one or more Third Party subcontractors, provided that, with respect to any new Third Party subcontractors (*i.e.*, any Third Party subcontractors that are not already engaged by Atara or any of its Affiliates, prior to the Effective Date, to provide services to Atara or any of its Affiliates with respect to the Product) that are dealing with material aspects of the Transition Plan, such right of Atara shall be subject to the prior approval of Partner (such approval shall not be unreasonably withheld, conditioned or delayed), provided further that, such approval shall be deemed given by Partner in the absence of a reply from Partner within [***] from Atara's request therefor.

14.2 **Partner.**

Subject to the terms and conditions of the Agreement, including, without limitation, Section 14.3 hereto, Partner shall have the right to carry out all or any part of its obligations under this Agreement or any Ancillary Agreement through (i) its Affiliates and Approved Sublicensees, and Distributors, or (ii) one or more Third Party subcontractor(s) that do not require a license under the Atara Intellectual Property to perform appointed activities under this Agreement.

14.3 **Responsibility For Subcontractors.**

Each Party shall ensure that each of its subcontractors or Approved Sublicensees (as applicable), if any, accepts and complies with all of the terms and conditions of this Agreement and such Party shall be responsible for all acts of such subcontractors or Approved Sublicensees as if such acts were its own.

ARTICLE 15
Term and Termination

15.1 **Term.**

This Agreement will commence on the Effective Date and, unless earlier terminated under this Article 15 shall expire following the last Commercial Sale of the Product in the Field in the Territory by or on behalf of Partner, its Affiliates or their Approved Sublicensees (the "**Term**").

15.2 **Termination for Material Breach, Transfer or Assignment, Insolvency Event.**

(a) Either Party may terminate this Agreement in the event of a material breach by the other Party of any material obligation of this Agreement in the overall context of the Agreement on [***] prior written notice to the other, specifying the nature of the breach, unless such other Party shall (i) cure such default within such [***] period or, (ii) if not capable of being remedied within such [***] period, communicate to the non-breaching Party a written remediation plan reasonably designed to cure such breach or default within a reasonable additional time period, not to exceed an additional [***] following expiration of the foregoing [***] period and diligently seeks to remedy the breach in accordance with the remediation plan. If the allegedly breaching Party disputes in good faith the material breach, this Agreement shall not be terminable by the non-breaching Party until it has been determined by arbitration under Section 16.12(c) that this Agreement was materially breached by the breaching Party and then only if the breaching Party has not cured such material breach within [***] following such arbitration determination. If the material breach is due to an Approved Sublicensee or Distributor of Partner, the termination of the license or sublicense with such Approved Sublicensee or Distributor within [***] of the notice of breach would be deemed to cure such breach for the purposes of this Section 15.2(a). Notwithstanding the foregoing, in the event of a material breach by either Party with respect to (A) the Initial Territory (and not the Additional Territory), then the non-breaching Party's termination rights arising from such breach shall be limited to the Initial Territory (as a whole), or (B) the Additional Territory (and not the Initial Territory), then the non-breaching Party's termination rights arising from such breach shall be limited to the Additional Territory (as a whole).

(b) Notwithstanding the provisions of Section 15.2(a), either Party may terminate this Agreement on written notice with immediate effect upon the Insolvency Event of the other Party. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to intellectual property as defined in Section 101 of such Code. The Parties agree that Partner may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, in the event Partner elects to retain its rights as a licensee under such Code, Partner shall be entitled to complete access to any Licensed Intellectual Property and all embodiments of such technology.

15.3 **Termination for Patent Challenge.**

If Partner commences or actively participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts in writing any claim

challenging or denying the validity or enforceability of any patent claim in the Atara Intellectual Property, then Atara shall have the right, in its sole discretion, to terminate this Agreement upon providing Partner [***] prior written notice of termination. In addition to all other rights and remedies available to Atara for any breach of this provision by Partner, in the event that any such challenge is not successful, then Partner shall reimburse Atara for all costs and expenses, including but limited to attorney's fees, incurred by Atara incurred as a result of defending against such challenge.

15.4 **Termination for Convenience by Partner.**

Partner shall be permitted to terminate this Agreement (i) in its entirety, (ii) on a Region-by-Region basis, and (iii) elsewhere in the Territory on a country by country basis, at will, (a) prior to the Manufacturing Transition Date, with [***] prior written notice to Atara, and (b) on or after the Manufacturing Transition Date, with [***] prior written notice to Atara. During the period after providing Atara a notice to terminate pursuant to this Section 15.4 and prior to the effective date thereof, this Agreement will remain in full force and effect and Partner shall continue (and shall cause all its Affiliates, Approved Sublicensees and Distributors to continue) to perform Partner's obligations and applicable activities under this Agreement in the Terminated Countries or worldwide (in the event of a termination of this Agreement in its entirety) as applicable.

15.5 **Termination for Safety Reasons.**

Partner shall be permitted to terminate the Agreement for Safety Reasons upon [***] written notice to Atara, but only after consulting with Atara at least [***] on Partner's assessment with respect to such Safety Reasons. In this regard, "**Safety Reasons**" shall mean that, based upon all relevant scientific data, there are safety and public health issues relating to the Product such that the medical benefit/risk ratio of such Product is sufficiently unfavorable as to materially compromise the welfare of patients so that use in patients is no longer justifiable. Upon termination for Safety Reasons pursuant to this Section 15.5, Partner shall be responsible for activities relating to recall of Product in all countries of the Territory, as applicable, at their sole cost and expense.

15.6 **Alternative to Termination for Material Breach.**

If Atara has materially breached or defaulted in the performance of any of its material obligations hereunder with respect to (a) the transition activities set forth in the Transition Plan or (b) of its obligations in Sections 7.11 and 7.12, and such breach is not curable or has not been cured within the cure period in Section 15.2 after written notice thereof was provided by Partner, then, [***].

15.7 **Consequences of Termination.**

(a) **Accrued Obligations**. The termination of this Agreement by either Party shall not release the other Party from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination, nor will any such termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this

Agreement, provided that any milestone payment that is achieved under Section 10.2(c) or Sections 10.2(e)-(h) during the termination notice period shall not be due.

(b) **Rights on Termination with respect to Terminated Countries**. In case of termination of this Agreement by either Party (unless as otherwise specified), this Section 15.7(b) shall only apply to the rights and activities related to each of the Terminated Countries:

(i) General Cooperation.

(A) The Parties shall use reasonable efforts to coordinate activities with respect to the Development of the Product in each Party's respective territory (*i.e.*, with respect to Atara, all of the Terminated Countries and, with respect to Partner, the Territory). Without limiting the foregoing, each Party shall (1) promptly notify the other Party in writing of any communication relating to the Product received from any Regulatory Authority that may be materially relevant to the other Party in such Party's territory and (2) promptly notify the other Party of any information it receives regarding any threatened or pending action or communication by or from any Regulatory Authority, which may adversely affect the exploitation or regulatory status of the Product in the other Party's territory.

(B) The Parties shall use reasonable efforts to coordinate activities with respect to the Commercialization of the Product in each Party's respective territory.

(ii) Wind-down Period.

(A) Partner shall use Commercially Reasonable Efforts to effect a smooth termination of the Agreement, including by performing the activities set forth in Sections 15.7(b)(ii)(B), 15.7(b)(ii)(C) and 15.7(b)(ii)(D), for a period not exceeding [***] following the termination of the Agreement ("**Wind-down Period**").

(B) At Atara's sole election, (i) Partner and Atara (or Partner and Atara's designee) shall, negotiate in good faith (during the Wind-down Period) and enter into (as soon as reasonably practicable and, in any event, prior to the expiration of the Wind-down Period) a manufacturing and supply agreement (containing the same framework as that contained in the Original Manufacturing and Supply Agreement or MSA, as applicable) for the Manufacture and supply to Atara (or its designee) of Atara's and its Affiliates' and licensees (or sublicensees, as applicable) requirements of Product in the Terminated Countries, [***], or (ii) Partner shall provide Atara with reasonable assistance in Atara's negotiation of Third Party arrangements with Partner's then-current suppliers for the Product, at Atara's costs.

(C) Each Party shall use Commercially Reasonable Efforts to cooperate with the other to effect a smooth and orderly wind down and transition to Atara (or its designee) of the activities related to the Product during the

Wind-down Period.

(D) Partner shall provide Atara with country-specific Promotional Materials for use limited to the Product, excluding any trademarks and logos that are specific to Partner. Partner agrees to provide Atara with country-specific Promotional Materials and to assign on reasonable commercial terms to be agreed by the Parties all rights in and to any Product Trademarks, other than Product Trademarks of Partner, specific to the Product that Partner or any of its Affiliates used or intended to use in connection with Product(s) in the Terminated Countries. It is understood that such assignment shall not include the name of Partner or any of its Affiliates, nor the corporate logo, service mark, or trademark for Partner or for any of its Affiliates as a corporate entity.

(iii) Licenses. Upon termination of this Agreement in all or in part by either Party, all licenses granted by Atara to Partner, including any license to Manufacture Product in (or for use in) the Terminated Countries or the Territory, as applicable, shall terminate, and Partner and its Affiliates, Approved Sublicensees and Distributors shall cease all Development, Manufacturing, Regulatory, and Commercialization activities under this Agreement, in each case, with respect to the Terminated Countries or the Territory, as applicable. Further, the following provisions shall apply to the Terminated Countries:

(A) Assignment of Regulatory Filings and Market Authorizations. Partner shall assign, or cause to be assigned, to Atara any and all Regulatory Filings, Marketing Authorizations and Pricing Approvals held in Partner's (or its Affiliates') name and relating to Product (or to the extent not so assignable, Partner shall take all reasonable actions to make available to Atara the benefits of) all Regulatory Filings, Marketing Authorizations and Pricing Approvals for the Product in the Terminated Countries. In each case, unless otherwise required by any applicable Law or regulation or requested by Atara, the foregoing assignment (or availability) shall be made within a reasonable period of time mutually agreed between the Parties. On or prior to the effective date of termination, Partner shall also provide Atara with copies of all such regulatory documentation.

(B) Approved Sublicensees. Any contracts with Approved Sublicensees and/or Distributors engaged by Partner (or its Affiliates) in the Terminated Countries shall, upon Atara's request, be assigned to Atara (or its designee) to the furthest extent possible. Partner shall use Commercially Reasonable Efforts, and cause its Affiliates to use Commercially Reasonably Efforts, to waive any exclusive dealing obligations of such Approved Sublicensees and/or Distributors, as applicable, with respect to the applicable sublicense agreement(s), and to provide to Atara information relevant to such sublicense agreement(s) and make introductions to such Approved Sublicensees and/or Distributors so that Atara may enter into direct discussions with such Approved Sublicensees and/or Distributors to secure the relevant items or services.

(C) Assignment of Product Trademarks and Domain Names. Upon the effective date of termination, Partner shall promptly assign, or cause to be assigned, to Atara (or its designee) any and all Product Trademarks, Product Trade Dress, and Product-specific website domain names, logos and slogans in the Terminated Countries, that were assigned to Partner pursuant to Section 7.6(a).

(D) Partner Trademarks. Upon the effective date of termination, Partner agrees to assign on reasonable commercial terms to be agreed by the Parties all rights in and to any trademarks owned by Partner that are specific to the Product that Partner, its Affiliates, and Approved Sublicensees used or intended to use in connection with the Product in the Terminated Countries. It is understood that such assignment shall not include the name of Partner or any of its Affiliates or Approved Sublicensees, nor the corporate logo, service mark, or trademark for Partner or for any of its Affiliates or Approved Sublicensees as a corporate entity.

(E) Partner Intellectual Property. Partner shall grant to Atara a non-exclusive, worldwide, transferable, perpetual and irrevocable license, with the right to sublicense through multiple tiers Partner Intellectual Property (including Development Data included therein other than any Licensed Back Data) as it exists at the time of such termination of this Agreement and that are necessary to research, develop, make, have made, use, sell, offer for sale, import, and otherwise exploit the Product and any related companion diagnostics, and to conduct or have conducted Cell Selection in the Field, subject to the Parties entering into a commercially reasonable, mutually-agreed license; provided however, that if termination is due to a material breach by Partner under Section 15.2(a), then the foregoing license shall be provided on a fully paid basis.

(F) Development Data. Partner shall and hereby does grant to Atara a non-exclusive, fully paid-up, transferable, perpetual and irrevocable license, with the right to sublicense (through multiple tiers) any and all Licensed Back Data to the extent necessary for Atara to research, Develop, make, have made, use, sell, offer for sale and import the Product for distribution and use in the Terminated Countries, as well as to conduct or have conducted Cell Selection in the Terminated Countries.

(G) Right of Reference. Without limiting Section 5.6, Atara (or its designee) shall have the right to cross-reference the Regulatory Filings Controlled by Partner under this Agreement relating to the Product (including any DMF Controlled by Partner and its Approved Sublicensees) and to access such Regulatory Filings for, (x) with respect to Licensed Back Data, any activity relating to obtaining or maintaining Regulatory Approval for the Product outside the Territory, (y) with respect to Development Data other than Licensed Back Data, subject to the Parties entering into a commercially reasonable, mutually-agreed license agreement, for any activity relating to obtaining or maintaining Regulatory Approval for the Product outside the Territory.

(iv) Restrictive Covenants.

(A) To the extent permitted by applicable Laws, Partner hereby covenants and agrees that it shall not (and shall ensure its Affiliates, Approved Sublicensees and Distributors shall not), either directly or indirectly, market, promote, distribute or sell or otherwise engage in the Commercialization of Product into or within countries outside of the Territory. Without limiting the generality of the foregoing, with respect to such countries outside of the Territory, Partner shall not (and shall ensure its Affiliates, Approved Sublicensees and Distributors shall not) (i) engage in any promotional, advertising, educational, scientific communications, medical affairs, or similar activities relating to the Product directed to customers or other persons, entities or organizations located in such countries, or (ii) solicit orders from any prospective purchaser located in such countries, provided in each case that Partner, in alignment with plans discussed in good faith with Atara, shall not be restricted from presenting the Product in international congresses, conferences or meetings outside the Territory organized by a professional society outside the Territory, conducting market research outside the Territory with prior consultation, and in coordination with Atara, or from interacting with key opinion leaders outside the Territory, each in connection with the Product.

(B) To the extent permitted by applicable Laws, and except in order to perform its obligations under this Agreement, Atara hereby covenants and agrees that it shall not (and shall ensure its Affiliates, distributors of the Product, and sublicensees of the Product shall not), either directly or indirectly, market, promote, distribute or sell or otherwise engage in the Commercialization of Product into or within countries in the Territory. Without limiting the generality of the foregoing, with respect to such countries inside the Territory, Atara shall not (and shall ensure that its Affiliates, distributors of the Product, and sublicensees of the Product will not) (i) engage in any promotional, advertising, educational, scientific communications, medical affairs, or similar activities relating to the Commercialization of Product directed to customers or other persons, entities or organizations located in such countries, or (ii) solicit orders from any prospective purchaser located in such countries, provided in each case that Atara, in alignment with plans discussed in good faith with Partner, shall not be restricted from presenting the Product in international congresses, conferences or meetings inside the Territory organized by a professional society inside the Territory, conducting market research inside the Territory with prior consultation and in coordination with Partner, or from interacting with key opinion leaders inside the Territory, each in connection with the Product.

(v) Intellectual Property Matters.

(A) Any and all rights relating to patent prosecution and enforcement of Atara Intellectual Property granted to Partner under this Agreement will terminate in the Terminated Countries.

(c) **Additional Rights on Termination of the Agreement (in its Entirety).** In case of termination of this Agreement in its entirety, by either Party pursuant to Section 15.2(a)

or 15.2(b), by Atara pursuant to Section 15.3, or by Partner pursuant to Sections 15.4 or 15.5, then in addition to Sections 15.7(b), and notwithstanding anything to the contrary contained therein, this Section 15.7(c) shall apply:

(i) Inventory. Except in the case of a termination for convenience by Partner pursuant to Section 15.4, Partner shall return to Atara, [***], in resalable form, its remaining inventory of the Product following the termination of this Agreement during the Wind-down Period. Following a termination for convenience by Partner pursuant to Section 15.4, Partner shall return to Atara [***], in resalable form, its remaining inventory of the Product during the Wind-down Period.

(ii) Clinical Studies. In the event Partner is the sponsor of or is responsible for conducting any ongoing Clinical Studies, other than the Current Studies, of the Product following the date a notice of termination has been issued by Atara or Partner, as applicable, Partner shall be entitled to complete or wind down such activities, unless Atara requests that they be transitioned to Atara (or Atara's designee), in which case Partner shall use Commercially Reasonable Efforts to support such transition to Atara (or Atara's designee), [***]. In the event Partner delivers a notice of termination pursuant to any of Section 15.2 or 15.5, to the extent that Partner is responsible for conducting any ongoing Current Study on the date of delivery of such notice, Partner shall be entitled to complete or wind down such activities, unless Atara requests that they be transitioned to Atara (or Atara's designee), in which case Partner shall use Commercially Reasonable Efforts to support such transition to Atara (or Atara's designee), [***]. In the event Partner delivers a notice of termination pursuant to Section 15.4, to the extent that Partner is responsible the costs for conducting any ongoing Current Study on the date of delivery of such notice, [***].

(iii) Transition of Contracts. As soon as reasonably practicable following the delivery or receipt, as applicable, of the notice of termination of the entire Agreement, Partner shall provide to Atara a schedule of all contracts in effect at the time of such notice, to which Partner or any of its Affiliates is a party, that are material to the Development, Cell Selection, Manufacture, Regulatory activities, or Commercialization, as applicable, of the Products and any related companion diagnostics, and to conduct or have conducted Cell Selection. Upon the effective date of termination, Partner shall assign (to the extent assignable) to Atara, upon specific request of Atara, any such contracts that are solely and exclusively related to the Product (including, without limitation, any and all Transferred Contracts and Bifurcated Contracts, that are then-still in effect, that were transferred and assigned to Partner pursuant to Section 4.3); provided that, to the extent any such contract is not assignable to Atara, Partner shall reasonably cooperate with Atara to assist Atara to arrange to continue to receive such services, [***].

(iv) Development Data. Notwithstanding anything to the contrary contained herein, upon the effective date of termination, Partner shall promptly assign, or cause to be assigned, to Atara any and all Development Data (including, without limitation, all Development Data assigned to Partner pursuant to Section 5.4), provided that, with respect to any Development Data within the Partner Intellectual Property, such assignment shall be subject to the Parties entering into a commercially reasonable, mutually-agreed

assignment agreement, as applicable; provided however, that if termination is due to a material breach by Partner under Section 15.2(a), then the foregoing assignment shall be free.

(v) Technology Transfer. As soon as reasonably practicable following the delivery or receipt, as applicable, of the notice of termination of the entire Agreement, Partner shall use Commercially Reasonable Efforts to (i) transfer to Atara (or its designee) any and all on-going or planned Development, Cell Selection, Manufacture, Regulatory activities, or Commercialization activities, and any and all technology, materials, and other Know-How required to enable Atara (or its designee) to perform such activities, and (ii) complete such technology transfer within the Wind-down Period.

15.8 **Termination Not Sole Remedy.**

Termination is not the sole remedy under this Agreement and, whether or not termination is affected and notwithstanding any provision contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE 16
General Provisions

16.1 **Antitrust Filings.**

(a) Each of Atara and Partner agrees to prepare and make appropriate filings under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("**HSR**"), and other antitrust requirements relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable after the Execution Date ([***]), but each Party shall otherwise bear its own costs in connection with such filings. The Parties agree to cooperate in the antitrust clearance process and to furnish promptly to the Federal Trade Commission ("**FTC**"), the Antitrust Division of the Department of Justice ("**DOJ**") and any other agency or authority, any information reasonably requested by them in connection with such filings. Each of the Parties agrees to use reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, and to assist and cooperate with the other Parties in doing, all things necessary, proper, or advisable to satisfy the Antitrust Conditions as promptly as practicable. With respect to the HSR filings and other filings made pursuant to this Section 16.1(a), each of Atara and Partner shall coordinate and cooperate in good faith. In furtherance of the foregoing, each Party agrees to: (i) promptly notify the other Party of any non-ministerial communication with the FTC, the DOJ, or any other agency or authority and, subject to applicable Law, discuss with and permit the other Party to review in advance and comment on (and such Party will consider any comments in good faith) any proposed written non-ministerial communication to any of the foregoing; (ii) not agree to participate in any non-ministerial meeting or discussion with the FTC, the DOJ or any other agency or authority in respect of any filings, investigation or inquiry concerning this Agreement unless it consults with the other Party in advance and, to the extent permitted by such the FTC, the DOJ or any other agency or authority, give the other Party the opportunity to attend and participate thereat; and (iii) promptly furnish the other Party with copies of all non-ministerial correspondence and communications (and memoranda setting forth the substance thereof) between them and their Affiliates and their respective representatives on the one hand, and the FTC, the DOJ or any other

agency or authority on the other hand, with respect to this Agreement; provided, however, that materials provided pursuant to the foregoing clauses (i) to (iii) may be redacted (A) to remove references concerning the valuation of the Parties or their respective Affiliates, (B) as necessary to comply with contractual arrangements and, (C) as necessary to address reasonable privilege or confidentiality concerns; provided, further, that each of the Parties may, as each deems advisable and necessary, reasonably designate any competitively sensitive material provided to the other under this Section 16.1 as "Outside Counsel Only Material" which such material and the information contained therein shall be given only to the outside antitrust counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient unless express permission is obtained in advance from the source of the materials. Neither Party shall withdraw its HSR filing, or agree with the FTC or DOJ to extend the period prohibiting consummation of the transactions contemplated by this Agreement, without the consent of the other Party, which will not unreasonably be withheld, conditioned or delayed.

(b) Other than the provisions of Section 11.5(c) (solely with respect to the first sentence thereof), Section 11.5(d) (solely with respect to the first sentence thereof) and Section 11.5(f) (collectively, the foregoing provisions, the "**Interim Covenants**"); this Section 16.1, Section 16.2 and Section 16.12; Article 13; and Article 1 (solely to the extent applicable to foregoing provisions referenced in this sentence), the rights and obligations of the Parties under this Agreement shall not become effective until the Effective Date, which shall not, in any event, occur before (i) the waiting period (and any extension thereof) applicable to the transactions contemplated by this Agreement under HSR shall have expired or earlier been terminated; (ii) no injunction or order (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement or any material portion hereof shall be in effect; and (iii) no judicial or administrative proceeding opposing consummation of all or any part of this Agreement shall be pending ((i), (ii), and (iii) together are the "**Antitrust Conditions**" and the date the Antitrust Conditions are satisfied is the "**HSR Clearance Date**" of this Agreement).

(c) If the HSR Clearance Date has not occurred within [***] after the Execution Date, this Agreement may either be (i) extended for an additional period of time to be mutually agreed between the Parties, or (ii) terminated by either Party upon written notice to the other.

16.2 **Effectiveness.**

(a) Atara may, no later than [***] following the HSR Clearance Date, deliver an updated Schedule 11.2 to Partner disclosing the existence of any material facts that occured between the Execution Date and the HSR Clearance Date that would cause any of the representations and warranties of Atara to be inaccurate as of the HSR Clearance Date. Notwithstanding anything to the contrary, if Atara provides notice to Partner within such [***] period that there are no updates to Schedule 11.2 (such notice, the "**Closing Notice**"), then all provisions of this Agreement shall become effective automatically upon Atara's delivery of such Closing Notice. Atara shall not be liable for a breach of its representations and warranties at the Effective Date if such facts occurred between the Execution Date and the HSR Clearance Date and are not attributable to a breach by Atara of the Interim Covenants. Partner shall have the right to review the updated Schedule 11.2 for a period of [***] after receipt thereof (such [***] period, the "**Schedule Review Period**"). At any time during the Schedule Review Period, Partner shall have the right to terminate this Agreement by delivery of a written notice to Atara (with such notice

specifying the information forming the basis for Partner's decision to terminate) if the revised information would have a Product Material Adverse Effect (such notice, the "**Recission Notice**"), provided that Atara shall have a period of [***] after receipt of such Recission Notice (such [***], the "**Notice Review Period**") to review such Recission Notice (including, without limitation, the information forming the basis of such decision to terminate) and to object to the existence of a Product Material Adverse Effect by written notice to Partner (such notice, the "**Objection Notice**"). If the Parties do not agree on the existence of a Product Material Adverse Effect within the Notice Review Period, then either Party may refer the matter for determination of the occurrence of a Product Material Adverse Effect in accordance with Section 16.12(c). If Partner does not deliver the Recission Notice to Atara within the Schedule Review Period, then Partner shall be deemed to have accepted the updated Schedule 11.2, and Schedule 11.2 attached to this Agreement as of the Execution Date shall be deemed to be superseded by the updated Schedule 11.2.

(b) All provisions of this Agreement shall become effective automatically upon the earliest to occur of:

(i) the date of Atara's delivery of a Closing Notice to Partner;

(ii) if Partner does not deliver the Recission Notice to Atara prior to the expiration of the Schedule Review Period, the date of expiration of the Schedule Review Period; or

(iii) if, pursuant to and in accordance with Section 16.2(a), (A) Partner delivers the Recission Notice to Atara, (B) Atara delivers the Objection Notice to Partner, (C) a Party refers the dispute regarding the existence of a Product Material Adverse Effect for determination by arbitration in accordance with Section 16.12(c), and (D) the final award rendered by the tribunal is that no such Product Material Adverse Effect exists, the date of such final award,

in any case (i), (ii) or (iii), without the need for further action by the Parties (such date, as applicable, the "**Effective Date**").

(c) Upon the occurrence of the Effective Date, the Original Commercialization Agreement shall automatically terminate, without the need for further action by the Parties. For clarity, and notwithstanding anything to the contrary herein, the Original Commercialization Agreement shall continue in full force and effect unless and until the occurrence of the Effective Date.

16.3 **Entire Agreement.**

Beginning on the Effective Date, this Agreement and the Ancillary Agreements, together with the Exhibits and all written amendments, modifications and supplements thereto constitute the entire agreement between the Parties and all prior negotiations, proposals and writings pertaining to this Agreement or the subject matter thereof (including the Original Commercialization Agreement), are hereby superseded. No modification of this Agreement will be effective unless in writing and signed by both Parties.

16.4 **Severability.**

In the event that any provision of the Agreement or the documents and instruments contemplated hereby is held by court of competent jurisdiction to be invalid, prohibited or unenforceable for any reason, unless narrowed by construction, the Agreement and the documents and instruments contemplated hereby shall be construed as if such invalid, prohibited or unenforceable provision had been more narrowly drawn so as not to be invalid, prohibited or unenforceable, or if such language cannot be drawn narrowly enough to satisfy such court, the court making any such determination shall have the power to modify in scope, duration or otherwise any such provision, but only to the extent necessary to make such provision or provisions enforceable in such court, and such provision then shall be applicable in such modified form. No narrowed construction, court modification, or invalidation of any provision of the Agreement and the documents and instruments contemplated hereby shall affect the construction, validity, or enforceability of such provision or of the Agreement and the documents and instruments contemplated hereby in any jurisdiction other than that upon which the decision of the court of competent jurisdiction shall govern.

16.5 **Assignment.**

This Agreement may not be assigned by either to any person, firm, partnership, corporation or other entity (including by operation of law, judicial process or otherwise) without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, provided that each Party may assign this Agreement, or any or all of the rights and obligations hereunder, to upon [***] written notice (a) without obtaining the other Party's prior written consent, to any of its Affiliates for as long as such entity remains an Affiliate, (b) in the case of Atara, without obtaining the Partner's prior written consent, to (i) an entity that acquires all or substantially all of the equity interests, business or assets to which this Agreement relates, whether by merger, acquisition, reorganization or otherwise, or (ii) to an entity located in the USA, European Union or United Kingdom solely with respect to the transfer or assignment of rights to receive payments (or any portion thereof) due to Atara under Sections 10.2 10.3 and 10.4 (and subject to set off rights as applicable), provided that, in connection with such a transfer or assignment, Atara may disclose to the transferee or assignee any reports or information provided to Atara regarding such payments under a written agreement containing non-disclosure and non-use provisions no less stringent than set forth in this Agreement, and *provided further* that if Partner reasonably believes the assignment in (ii) would materially and adversely affect Partner's ability to perform its obligations under this Agreement, the Partner shall be entitled to refuse such assignment; and (c) in the case of Partner, without obtaining Atara's prior written consent, to an entity that acquires all or substantially all of the equity interests, business or assets of Partner or Partner's commercial franchise within Partner's organization in which the Product is operated, whether by merger, acquisition, reorganization or otherwise. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Any assignment not in accordance with this Section 16.5 shall be null and void.

16.6 **Counterparts.**

This Agreement may be executed in any number of counterparts and by each of the

Parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signatures of the Parties transmitted by electronic means shall be deemed to be their original signatures for all purposes.

16.7 **Third Party Beneficiaries.**

Memorial Sloan Kettering Cancer Center is a Third Party beneficiary of this Agreement solely to the extent required in the MSK Agreement. Otherwise, this Agreement and each and every provision hereof and thereof are for the exclusive benefit of the Parties hereto and not for the benefit of any other third party.

16.8 **Force Majeure.**

If the performance of any part of this Agreement (except for any payment obligation under this Agreement) by either Party is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of such Party (including, fire, flood, earthquake, tsunami, embargo, power shortage or failure, acts of war, pandemic, insurrection, riot, terrorism, strike, lockout or other labor disturbance, acts of God or any acts, omissions or delays in acting of the other Party), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party shall use its reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

16.9 **Applicable Law.**

The Parties agree to conduct all activities under this Agreement in compliance with applicable Law. This Agreement will be governed by and in accordance with the laws of the State of Switzerland without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction.

16.10 **Waiver.**

Neither Party's failure to insist on performance of any term, condition, or instruction nor failure to exercise any right or privilege or its waiver of any breach, shall thereafter be construed to constitute a waiver of such term, condition, instruction, right or privilege. No consent or waiver, expressed or implied, by a Party to the performance by the other Party or of any breach or default by the other Party of its obligations hereunder shall be deemed or construed to be a consent or waiver to or of any other breach or default in the performance by such other Party of the same or any other obligations of such other Party hereunder. The giving of consent by a Party in any one instance shall not limit or waive the necessity to obtain such Party's consent in any future instance. No waiver of any rights under this Agreement shall be binding unless it is in writing and signed by the Party waiving such rights.

16.11 **Notices.**

Unless otherwise agreed by the Parties or specified in this Agreement, all communications between the Parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement shall be in writing in the English language, and (a) delivered personally, (b) sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, or (c) by electronic transmission or facsimile (complete transmission confirmed and a copy promptly sent by another permissible method of providing notice described in paragraph (a) or (b) above), to the following addresses of the Parties (or such other address for a Party as may be specified by like notice):

To Atara:

[***]

To Partner:

[***]

16.12 **Dispute Resolution.**

(a) **Referral to Senior Executives**. The Parties recognize that a dispute arising out of or in connection with this Agreement ("**Dispute**") may from time to time arise during the Term of this Agreement. Any such Dispute which cannot be resolved by good faith negotiations shall be referred, by written notice from either Party to the other, to the Executive Officers (or their respective designees) for resolution. The Executive Officers (or their respective designees) shall negotiate in good faith to resolve such Dispute through discussions promptly following such written notice. If the Executive Officers cannot resolve the Dispute within [***] of such written notice, or either Party concludes that the matter will not be so resolved, then, the provisions of Section 16.12(b) shall apply. If the Parties should resolve such Dispute pursuant to the procedures in this Section 16.12(a), a memorandum setting forth their agreement will be prepared and signed by both Parties, if requested by either Party.

(b) **Mediation**. If the Executive Officers (or their respective designees) cannot resolve the Dispute during the [***] period pursuant to Section 16.12(a), the Parties shall first refer the dispute to proceedings under the ICC Mediation Rules. Such mediation shall take place in [***] and shall be attended on behalf of each Party for at least one session by a senior businessperson with authority to resolve the Dispute.

(c) **Arbitration**. Any Dispute not resolved under the procedures in Section 16.12(b) within [***] following the filing of a request for mediation or within such other period as the Parties may agree in writing, such Dispute shall thereafter be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators, and the President of the Tribunal shall be nominated according to such Rules of Arbitration of the International Chamber of Commerce. The seat, or legal place, of arbitration shall be [***]. The language of the arbitration shall be English. The final award shall be rendered within [***] of the constitution

of the tribunal, unless the tribunal determines that the interest of justice requires that such limit be extended. Except as may be required to confirm or enforce a final award, or as may be required by applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

(d) **Non-Disclosure of Communications with Internal Counsel**. Notwithstanding any rights to the contrary under applicable procedural or substantive rules of Law, any communications exchanged between members of each Party's respective legal department and directors, employees or agents in connection with any disputes, investigations, administrative or other proceedings, shall not be requested, produced or otherwise used, to the extent such communications would have been covered by legal privilege and not disclosable, had these communications been exchanged between such Party and its external attorneys.

16.13 **Headings.**

Any headings used herein are for convenience in reference only and are not a part of this Agreement, nor shall they in any way affect the interpretation hereof.

16.14 **Interpretation.**

The captions to the articles and sections of this Agreement are not a part of this Agreement but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the words "including" and "includes" shall be deemed to be followed by the phrase "without limitation" or like expression; and (b) the singular shall include the plural and vice versa. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under generally accepted cost accounting principles, but only to the extent consistent with its usage and the other definitions in this Agreement. This Agreement shall not confer any benefits on any Third Parties and no Third Party may enforce any term of this Agreement.

16.15 **Further Assurances.**

Each Party hereto agrees that they will without further consideration execute and deliver such other documents and take such other actions as may be reasonably requested by the other Party to consummate more effectively the transactions and agreements contemplated hereby.

16.16 **No Partnership or Joint Venture.**

Nothing in this Agreement is intended, or shall be deemed, to establish a joint venture or partnership between Atara and Partner. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

16.17 **Survival.**

The following provisions of this Agreement, as well as the provisions of this Agreement which by their nature are intended to survive the termination, cancellation, completion

or expiration of this Agreement, shall continue as valid and enforceable obligations of the Parties notwithstanding any such termination, cancellation, completion or expiration: Article 1 (solely to the extent applicable to following provisions referenced in this sentence), and Article 16; Sections 2.3, 5.3, 6.4(b), 6.6 (solely to the extent that such audit relates to Product Commercialized during the Term), 7.6(c), 9.1; each of Sections 10.8, 10.9, 10.10, and 10.12 (solely, in each case, to the extent that such reports, records, payments and taxes apply to the period prior to the effective date of termination); Section 10.11 (solely to the extent that such Transition Costs, including without limitation any Excess Costs, accrue prior to the effective date of termination); Section 11.7; Sections 12.1-12.3 (solely with respect to Third Party Claims arising during the Term); Sections 12.4, 12.5, 13.1-13.8, 13.10, 15.7, and 15.8.

[Remainder of page intentionally left blank; signature page follows.]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

ATARA BIOTHERAPEUTICS, INC.	**PIERRE FABRE MEDICAMENT**
By: /s/ Pascal Touchon	By: /s/ Jean-Luc Lowinski
Name: Pascal Touchon	Name: Jean-Luc Lowinski
Title: President and Chief Executive Officer	Title: President
Date: 10/31/2023	Date: 10/31/2023

List of Exhibits:

EXHIBIT A [***]
EXHIBIT B [***]
EXHIBIT C [***]
EXHIBIT D [***]
EXHIBIT E [***]
EXHIBIT F [***]
EXHIBIT G [***]
EXHIBIT H [***]

EXHIBIT A [***]

[***]

EXHIBIT B [***]

[***]

EXHIBIT C [***]

[***]

EXHIBIT D [***]

[***]

EXHIBIT E [***]

[***]

EXHIBIT F [***]

[***]

EXHIBIT G [***]

[***]

EXHIBIT H [***]

[***]

SCHEDULE 1.199 [***]

[***]

Schedule 1.199

SCHEDULE 8.6(a) [***]

[***]

Schedule 8.6(b)

SCHEDULE 8.6(b) [***]

[***]

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SCHEDULE 10.11(b) [***]

[***]

Schedule 10.11(b)

SCHEDULE 11.2 [***]

[***]

Schedule 11.2

Exhibit 21.1

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of the Company as of December 31, 2023:

Subsidiary Legal Name	**State or other Jurisdiction of Incorporation or Organization**
Atara Biotherapeutics Australia Pty. Ltd.	Australia
Atara Biotherapeutics Ireland Limited	Ireland
Atara Biotherapeutics Switzerland GmbH	Switzerland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statements No. 333-199508, No. 333-204076, No. 333-209961, No. 333-214431, No. 333-219763, No. 333-223254, No. 333-229861, No. 333-236704, No. 333-249976, No. 333-253734, No. 333-259882, No. 333-263109, No. 333-266288, No. 333-269647, and No. 333-276360 on Form S-8 and registration statement No. 333-275256 on Form S-3 of our report dated March 28, 2024, relating to the consolidated financial statements of Atara Biotherapeutics, Inc. and subsidiaries (the "Company"), appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2023.

/s/ *DELOITTE & TOUCHE LLP*

San Francisco, California
March 28, 2024

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Pascal Touchon, certify that:

1.I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

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

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

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2024

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

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER

PURSUANT TO

SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Eric Hyllengren, certify that:

1.I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

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

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

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2024

/s/ Eric Hyllengren
Eric Hyllengren
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in connection with the Annual Report of Atara Biotherapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "Report"), Pascal Touchon, Chief Executive Officer of the Company, and Eric Hyllengren, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1)The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 28, 2024

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

/s/ Eric Hyllengren
Eric Hyllengren
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

ATARA BIOTHERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the "***Board***") of Atara Biotherapeutics, Inc. (the "***Company***") has determined that it is in the best interests of the Company to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of certain Incentive Compensation (as defined below) paid to Covered Officers (as defined below) of the Company under certain circumstances in the event of a restatement of financial results by the Company. The Board may delegate determinations to be made under this Policy to a committee of the Board (the "***Committee***"), and the Board and any such authorized Committee are collectively referred to in this Policy as the "***Board***."

This Policy shall be interpreted to comply with the requirements of U.S. Securities and Exchange Commission ("***SEC***") rules and Nasdaq Stock Market ("***Nasdaq***") listing standards implementing Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "***Dodd-Frank Act***") and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

This Policy shall be administered by the Board and, except as specifically provided herein and to the extent consistent with the rules and listing standards implementing Section 954 of the Dodd-Frank Act, the Board shall have full and final authority to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the Dodd-Frank Act. Any determination by the Board with respect to this Policy shall be final, conclusive and binding on all interested parties, including all Covered Officers and their beneficiaries, executors, administrators, and other legal representatives. The Board may amend or terminate this Policy at any time, subject to SEC rules and Nasdaq listing standards.

2. EFFECTIVE DATE

This Policy has been adopted by the Board on October 24, 2023, and shall apply to all Incentive Compensation paid or awarded on or after October 2, 2023.

3. DEFINITIONS

For purposes of this Policy, the following terms shall have the meanings set forth below:

"***Accounting Restatement***" means the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Covered Officer***" means a current or former "executive officer" of the Company within the meaning of Rule 10D-1 under the Securities Exchange Act of 1934, as amended.

*"**Incentive Compensation***" means any compensation that is granted, earned or vested based in whole or in part on the attainment of a financial reporting measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, whether or not presented within the Company's financial

statements or included in a filing with the SEC, including stock price and total stockholder return ("***TSR***"), including but not limited to performance-based cash, stock, options or other equity-based awards paid or granted to the Covered Officer. Compensation that is granted, vests or is earned based solely upon the occurrence of non-financial events, such as base salary, restricted stock or options with time-based vesting, or a bonus awarded solely at the discretion of the Board and not based on the attainment of any financial measure, is not subject to this Policy. Incentive Compensation is considered to have been received by a Covered Officer in the fiscal year during which the applicable financial reporting measure was attained or purportedly attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

"***Recoverable Incentive Compensation***" means Incentive Compensation received during the Recovery Period.

"*Recovery Period"* means the three completed fiscal years immediately preceding the date on which the Company is required to prepare the Accounting Restatement, as determined in accordance with this definition, or any transition period that results from a change in the Company's fiscal year (as set forth in Section 5608(b)(i)(D) of the Nasdaq Listing Rules). The date on which the Company is required to prepare an Accounting Restatement is the earlier to occur of (A) the date the Board or a Board committee (or authorized officers of the Company if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

4. **RECOUPMENT**

a. Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the amount to be recovered will be the excess of (i) the Recoverable Incentive Compensation received by the Covered Officer based on the erroneous data and calculated without regard to any taxes paid or withheld, over (ii) the Incentive Compensation that would have been received by the Covered Officers had it been calculated based on the restated financial information, as determined by the Board. For Incentive Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Accounting Restatement, then the Board shall determine the amount to be recovered based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received and the Company shall document the determination of that estimate and provide it to Nasdaq.

b. Sources of Recoupment. To the extent permitted by applicable law, the Board, in its discretion, may use any legal or equitable remedies that are available to the Company to seek recoupment from a Covered Officer, including but not limited to, recoupment from any of the following sources: direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; future payments of other Incentive Compensation; and cancellation of outstanding Incentive Compensation. To the extent permitted by applicable law, the Company may also offset the recoupment amount owed to the Company against any compensation or other amounts owed by the Company to the Covered Officer. Covered Officers shall be solely responsible for any tax consequences to them that result from the recoupment or recovery of any amount pursuant to this Policy, and the Company shall have no obligation to administer the Policy in a manner that avoids or minimizes any such tax consequences.

c. No-Fault Recovery. Recoupment under this Policy shall be required regardless of whether the Covered Officer or any other person was at fault or responsible for accounting errors that contributed to the need for the Accounting Restatement or engaged in any misconduct.

d. Exceptions. The compensation recouped under this Policy shall not include Incentive Compensation received by a Covered Officer (i) prior to beginning service as a Covered Officer or (ii) if he or she did not serve as a Covered Officer at any time during the performance period applicable to the Incentive Compensation in question. The Board may determine not to seek recovery from a Covered Officer in whole or part to the extent it determines in its sole discretion that such recovery would be impracticable because (A) the direct expense paid to a third party to assist in enforcing recovery would exceed the recoverable amount (after having made a reasonable attempt to recover the erroneously awarded Incentive Compensation and providing corresponding documentation of such attempt to Nasdaq), (B) recovery would violate the home country law that was adopted prior to November 28, 2022, as determined by an opinion of counsel licensed in the applicable jurisdiction that is acceptable to and provided to Nasdaq, or (C) recovery would likely cause the Company's 401(k) plan or any other tax-qualified retirement plan to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

5. SEVERABILITY

If any provision of this Policy or the application of any such provision to any Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

6. NO IMPAIRMENT OF OTHER REMEDIES

This Policy shall be without prejudice to any other rights or remedies that the Company, or the Board may have, and does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, whether arising under applicable law (including pursuant to Section 304 of the Sarbanes-Oxley Act of 2002), regulation or pursuant to the terms of any other policy of the Company, employment agreement, equity award, cash incentive award or other agreement applicable to a Covered Officer, including termination of employment, institution of civil proceedings, or reporting of any misconduct to appropriate government authorities. Notwithstanding the foregoing, there shall be no duplication of recovery of the same Incentive Compensation under this Policy and any other such rights or remedies.

7. NO INDEMNIFICATION

The Company shall not indemnify any Covered Officer or pay or reimburse the premium for any insurance policy to cover any losses incurred by such Covered Officer under this Policy or any claims relating to the Company's enforcement of rights under this Policy.