## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

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

For the fiscal year ended December 31, 2022

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☐ TRANSITION 1	REPORT PURSUANT TO SECTION 13 OR	. ,	IGE ACT OF 1934
	F	For the transition period from to Commission File Number 001-36548	
		SIOTHERAPEUT name of Registrant as specified in its Ch	,
	Delaware		46-0920988
	state or other jurisdiction of incorporation or organization) 380 Conejo Spectrum Street, Suite 200		(I.R.S. Employer Identification No.)
	Thousand Oaks, CA		
	(Address of principal executive offices)		91320 (Zip Code)
	Registrant's	telephone number, including area code: (80	
Securities registered pursuant	to Section 12(b) of the Act:		
· ·	Title of each class Stock, par value \$0.0001 per share,	Trading Symbol(s) ATRA	Name of each exchange on which registered  The Nasdaq Stock Market LLC
Securities registered pursuant	t to Section 12(g) of the Act: None		
Indicate by check mark if the	Registrant is a well-known seasoned issuer, as defin	ned in Rule 405 of the Securities Act. YES $\square$ N	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 $\square$ NO $\boxtimes$	
	her the Registrant: (1) has filed all reports required to s required to file such reports), and (2) has been subj		es Exchange Act of 1934 during the preceding 12 months (or for such shorter lays. YES $\boxtimes$ NO $\square$
	her the Registrant has submitted electronically every such shorter period that the Registrant was required t		pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the
	her the Registrant is a large accelerated filer, an acceled filer", "smaller reporting company" and "emerging		reporting company, or an emerging growth company. See definitions of "large inge Act.
Large accelerated filer			Accelerated filer
Non-accelerated filer			Small reporting company
Emerging growth company			
If an emerging growth compa pursuant to Section 13(a) of t	•	ted not to use the extended transition period for	complying with any new or revised financial accounting standards provided
•	her the registrant has filed a report on and attestation C. 7262(b)) by the registered public accounting firm		reness of its internal control over financial reporting under Section 404(b) of the
Indicate by check mark wheth	her the Registrant is a shell company (as defined in I	Rule 12b-2 of the Exchange Act). YES 🗆 NO	$\boxtimes$
The aggregate market value of	of common stock held by non-affiliates of the Regist	rant, based on the closing sales price for such s	tock on June 30, 2022 as reported by The Nasdaq Stock Market, was

\$715,382,568. This calculation excludes 2,522,882 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 January 31, 2023 was 95,926,711.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2023 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," "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;
- •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<sup>®</sup> for patients with Epstein-Barr virus with post-transplant lymphoproliferative disease (EBV+PTLD);
- •the potential indications for our product and product candidates;
- •commercialization of Ebvallo<sup>TM</sup> in the European Union (EU) and our Commercialization Agreement with Pierre Fabre Medicament, including potential milestone and royalty payments under the agreement;
- 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;
- 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 ability to continue as a going concern;
- •our ability to enter into favorable commercialization arrangements with third parties to commercialize our product and 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, manufacturing organizations 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;
- •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 COVID-19 to our business and operations, as well as the businesses and operations of third parties on which we rely;
- •our ability to attract and retain qualified personnel and to our business, operations and financial condition; and
- •timing and costs related to the qualification of our contract manufacturing organizations' (CMO) manufacturing facilities 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; which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in Southern California and Colorado and at our clinical trial sites, as well as the business or operations of our third party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of our capital 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 cumulative losses since our inception and anticipate that we will continue to incur substantial losses for the foreseeable future;
- •we currently have only one approved product and no revenues from commercialization of any products and may never achieve profitability;
- •we are generally early in our development efforts, have only a small number of product candidates in clinical development, and we will need to successfully complete preclinical and clinical testing of our product candidates before we can seek regulatory approval and potentially generate commercial sales from them;
- •we will require substantial additional financing to achieve our goals, which may not be available to us on acceptable terms, or at all;
- •our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel;
- •the results of preclinical studies or earlier clinical studies are not necessarily predictive of future results, and 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, both in the U.S. and international jurisdictions, involves a lengthy and expensive process with an uncertain outcome and even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties;
- •our T-cell immunotherapy product candidates and our next-generation CAR T programs represent new therapeutic approaches that could result in heightened regulatory scrutiny 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 COVID-19 pandemic continues to impact our business and operations and could materially and adversely affect our business and operations in the future, as well as the businesses and operations of third parties on which we rely;

- •our success depends upon our ability to obtain and maintain sufficient intellectual property protection for our product and product candidates, and we may not be able to protect our intellectual property rights throughout the world;
- •our principal stockholders own a significant percentage of our stock and, collectively, will be able to exert significant control over matters subject to stockholder approval;
- •our 2022 workforce reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business; and
- •we may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture some or all of our product and product candidates.

#### 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) for commercial sale in the European Union (EU) by the European Commission (EC) under the proprietary name Ebvallo<sup>TM</sup>. We are the most advanced allogeneic T-cell immunotherapy company and intend to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-driven diseases or other serious diseases through incorporation of engineered chimeric antigen receptors (CARs) or T-cell receptors (TCRs). Atara is applying this one platform, that does not require TCR or HLA gene editing, to create a robust pipeline. Our strategic priorities are:

- Tab-cel®: Atara's most advanced T-cell immunotherapy program, tab-cel, has received MAA for commercial sale in the EU under the proprietary name Ebvallo and is partnered with Pierre Fabre Medicament (Pierre Fabre) for commercialization in Europe and potential commercialization, if approved, in select emerging markets. Tab-cel (tabelecleucel) is currently in Phase 3 development in the U.S. for patients with EBV-driven post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-driven diseases;
- •ATA188: T-cell immunotherapy targeting EBV antigens, believed to be important for the potential treatment of primary and secondary progressive multiple sclerosis, and is currently in Phase 2 development; and
- •ATA3219: Allogeneic CAR T targeting CD19, currently in preclinical development, and being developed as a potential best-in-class product intended to target B-cell malignancies, 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 clinical and preclinical programs, including ATA2271, an autologous CAR T immunotherapy currently in Phase 1 development targeting solid tumors expressing the tumor antigen mesothelin; and ATA3271, an allogeneic CAR T immunotherapy currently in preclinical development targeting mesothelin.

Our T-cell immunotherapy platform includes the capability to progress both allogeneic and autologous programs and is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. For our allogeneic programs, we select the appropriate set of cells for use based on a patient's unique immune profile. One of our contract manufacturing organizations (CMOs) has completed commercial production qualification activities for tab-cel and our other CMOs are currently in the process of completing commercial production qualification activities for tab-cel while we build inventory according to our 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 following regulatory approval. We retain full rights to tab-cel in other major markets, including North America, Asia Pacific and Latin America. 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 to receive 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 Territory, and (ii) the supply price mark up on Ebvallo purchased by Pierre Fabre. Additionally, we also 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 HCR Molag Fund L.P (HCRx) for a total investment amount of \$31.0 million, subject to a cap between 185% and 250% of the total investment amount by HCRx.

In December 2020, we entered into a Research, Development and License Agreement with Bayer (the Bayer License Agreement) pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271. In March 2021, as contemplated by the

Bayer License Agreement, we entered into (i) a Manufacturing and Supply Agreement (Bayer Manufacturing Agreement); (ii) a Pharmacovigilance Agreement; (iii) a Quality Agreement; and (iv) a Technology Transfer Agreement, in each case, with Bayer, to further advance our collaboration with Bayer. 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 (Bayer Termination Agreement) with Bayer that terminated the Bayer Agreements and returned full product development rights for ATA2271 and ATA3271 to Atara effective as of July 31, 2022.

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

Our research facilities in Thousand Oaks, California (ARC) and Aurora, Colorado contain our translational and pre-clinical 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, at which time we assigned the lease for the ATOM Facility to FDB in connection with the closing of the Fujifilm Transaction. We also entered into a Master Services and Supply Agreement with FDB (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 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. Based on our expectations of patients and demand for product in the EU, we believe our current inventory of Ebvallo is sufficient to supply commercial demand in the EU until the end of 2023.

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 of our product candidates. In February 2023, we amended the CRL MSA to extend the term until the earlier of September 30, 2023 or receipt of certain batches of our product and product candidates.

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 August 2022, we announced a reduction in workforce of approximately 20% of total workforce to focus our activities as a leaner organization centered on research and development to further advance our innovative pipeline, while reducing cash burn. The workforce reduction is expected to include total restructuring charges of approximately \$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 Act and continuing health care coverage over 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 will be paid between October 2022 and November 2023. All of the severance costs represent cash expenditures.

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 otherwise payable by Pierre Fabre to us under the Pierre Fabre Commercialization Agreement. The total royalties and milestones payable to HCRx under the HCRx Agreement are capped between 185% and 250% of the total investment amount by HCRx, dependent upon the timing of such royalties and milestones.

## Pipeline

Our pipeline is summarized below:

Program	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3	Registration
Tab-cel <sup>®</sup> or Ebvallo™ (tabelecleucel)	RR EBV+ PTLD following HCT and SOT	EBV	ALLELE Study				EU Approved
	Multi-Cohort (Label-Expansion): EBV+ cancers <sup>(1)</sup>	EBV					
	Nasopharyngeal carcinoma <sup>(2)</sup>	EBV					
ATA188	Progressive MS	<b>EBV</b> (3)	EMBOLD Study				
ATA2271 (Autologous)	Autologous CAR T Solid tumors <sup>(4,5)</sup>	Mesothelin					
ATA3271 (Allogeneic)	Off-the-shelf, allogeneic CAR T Solid tumors <sup>(4)</sup>	Mesothelin					
ATA3219 (Allogeneic)	Off-the-shelf, allogeneic CAR T B-cell malignancies	CD19					
ATA3431 (Allogeneic)	Off-the-shelf, allogeneic CAR T B-cell malignancies	CD19/CD20					

Except for Ebvallo in the EU, these investigational agents are not approved by any regulatory agencies. 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

We have entered into an agreement with Pierre Fabre to commercialize Tab-cel® for EBV+ cancers in Europe, Middle East, Africa, and other select emerging markets.

Other programs: EBV vaccine, other solid tumor, and infectious disease programs

(1)Phase 2 multi-cohort initiated in Q3 2020, with possible indications including EBV+ PTLD with CNS involvement, EBV+ PID/AID LPD, EBV+ LMS and other potential EBV-associated diseases; Initial phase 2 data expected in 2023.

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

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

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

(5)Our CAR T collaboration with MSK will focus on development of a next-generation, mesothelin-targeted CAR T using novel 1XX CAR signaling and PD-1 dominant negative receptor (DNR) checkpoint inhibition technologies.

## Ebvallo<sup>TM</sup> (Tab-cel<sup>®</sup>)

EBV+ PTLD

Since its discovery as the first human oncovirus, EBV has been implicated in the development of a wide range of diseases, including lymphomas and other cancers. EBV is widespread in human populations and persists as a lifelong, asymptomatic infection. In healthy individuals, a small percentage of T cells are devoted to keeping EBV in check. In contrast, immunocompromised patients, such as those undergoing hematopoietic cell transplants (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<sup>®</sup> (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<sup>®</sup> (Ebvallo™) is an allogeneic EBV-specific T-cell immunotherapy that is approved in the EU 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 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. We retain full rights to tab-cel in other major markets, including North America, Asia Pacific and Latin America. 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 cap between 185% and 250% of the total investment amount by HCRx.

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 relapsed or refractory 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 is planning to commence Ebvallo launch activities in the first European countries in the first quarter of 2023. Under the "exceptional circumstances" marketing authorization, Pierre Fabre is subject to certain ongoing post-marketing obligations to continue confirmation of the benefits of Ebvallo. Since Ebvallo was approved under the exceptional circumstances regulatory pathway, continuation of the Ebvallo marketing authorization is 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.

In October 2022, we filed the MAA for Ebvallo with the Medicines and Healthcare Products Regulatory Authority (MHRA) in the United Kingdom (UK) and anticipate a decision on the potential approval of the MAA in the UK by March 2023.

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 February 2023, we held a meeting with the FDA on clinical aspects for a potential BLA submission for tab-cel. Following this discussion, we and the FDA expect to hold another meeting to further discuss CMC matters relating to a potential BLA submission for tab-cel, including aspects related to comparability that may support pooling clinical data from different process versions. We expect to provide a further update on a potential BLA submission for tab-cel in the second quarter of 2023.

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 need 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 and are actively opening sites and enrolling in six patient populations, including four within IA-LPDs and two in other EBV-driven diseases, in both the U.S. and EU. We continue to enroll

patients in this study. We anticipate investigating additional label expansion opportunities with this multi-cohort study. Data from this study is expected in 2023.

Tab-cel for NPC

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

Our Phase 1b study, which was initiated in 2018, achieved its safety endpoints and stable disease in some patients. Due to the evolving treatment landscape of EBV-driven nasopharyngeal carcinoma (NPC), we are not actively conducting any development activities while we reassess our approach and the development and regulatory pathways for patients with platinum resistant or recurrent EBV-drive NPC.

## ATA188

Multiple Sclerosis

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

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

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

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

ATA188 for MS

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

Our T-cell immunotherapy product candidate utilizing this technology, ATA188, is an off-the-shelf EBV-specific T-cell preparation that utilizes an MS-specific targeted antigen recognition technology that enables the T cells we administer to selectively identify cells expressing the EBV antigens that we believe are important for the potential treatment of MS. ATA188 is designed to selectively target only those cells which are EBV-positive while sparing those that are not. Recent studies published in *Science* and *Nature* provide new epidemiological data suggesting that EBV is the leading cause of MS, and mechanistic data suggesting EBV infection can initiate and propagate the autoimmune attack on the brain in MS. We believe that eliminating only EBV-positive B cells and plasma cells has the potential to benefit some patients with PMS and SPMS.

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

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

We are currently progressing an open-label extension (OLE) of the Phase 1 study of ATA188 for patients with primary and secondary PMS. We presented long-term two-year clinical data from the OLE and translation data from the Phase 1 study in October 2021 at the 37<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). Based on the clinical data, most patients either demonstrated sustained disability improvement or stable disease. The presentation also featured new imaging biomarker data considered to reflect the state of myelination in the central nervous system, known as magnetization transfer ratio (MTR). MTR may provide important insights into the mechanism of EDSS improvement in our clinical assessment of ATA188.

In June 2020, we enrolled the first patient in our Phase 2, randomized, double-blind, placebo-controlled dose-expansion trial (EMBOLD) to evaluate the efficacy and safety of ATA188 in patients with PMS and we continue to enroll patients in this study. Based on the data from the Phase 1a portion of the study, we selected the cohort 4 dose for enrollment in the Phase 2 EMBOLD study. In addition to measuring change in disability measures compared to baseline, especially SDI over time, the study also includes multiple measures of patients' function as well as various biomarkers.

In March 2022, we presented updated Phase 1 and OLE data that demonstrated 20 out of 24 patients have had either EDSS improvement or EDSS stability throughout their observation in the study with up to 42 months follow-up; 33% of patients in the high-dose cohorts achieved confirmed expanded disability status scale (EDSS) improvement at the 12-month timepoint.

In January 2021, we discussed updates to the design of the EMBOLD study with the FDA and gained alignment on several points, as well as potential registrational studies: (i) a disability improvement endpoint is appropriate, with the FDA articulating a preference for EDSS improvement; (ii) the criteria used to enroll the study population of SPMS and PPPMS are appropriate; and (iii) the Phase 2 trial should run for at least 12 months, and a properly conducted interim analysis is appropriate. We also submitted a protocol amendment to the FDA, increasing the number of patients to 80, changing the primary end point of the study to EDSS disability improvement and maintaining the biological and functional endpoints.

In June 2022, we completed the planned Interim Analysis (IA) of the EMBOLD study and determined no sample size adjustment or modification would be made to the study. Based on the analysis of the EMBOLD data available at the time of the IA, there was not a sufficient dataset to draw conclusions about the predictive value of six months EDSS improvement for 12 months EDSS improvement. The Independent Data and Safety Monitoring Committee (IDSMC) believes the six-month interim endpoint may be an inaccurate measure of the potential of this intervention in this condition. The IDSMC recommended the study continue without sample size adjustment or modification. Based on enrollment in the EMBOLD at the end of July, approximately 90 patients are planned to be included in the read out of the study primary endpoint of confirmed disability improvement of Expanded Disability Status Scale (EDSS) at 12 months. Communication of such data is planned to occur in an appropriate forum in October 2023.

In October 2022, we presented new magnetic resonance imaging (MRI) biomarker imaging and OLE clinical data from the Phase 1 study of ATA188 in progressive MS at the 2022 European Committee for Treatment and Research In Multiple Sclerosis (ECTRIMS) conference.

ATA188 has received fast track designation for treatment of PPMS and SPMS from the FDA.

We continue to plan for Phase 3 readiness, including interacting with the FDA based on two fast track designations, and further developing our proprietary large-scale bioreactor manufacturing process.

## ATA3219

We are also developing ATA3219, a potential best-in-class, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies, leveraging our next-generation 1XX CAR co-stimulatory domain and EBV T-cell platform and does not require TCR or human leukocyte antigen (HLA) gene editing. 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.

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.

We continue to make progress on the ATA3219 manufacturing process for scale-up. We currently intend to file an IND for the ATA3219 program in the second quarter of 2023 following completion of process optimization and manufacturing runs in the GMP manufacturing suites of our CMO. Our EBV CD19 CAR T program is enriched for a memory T-cell phenotype and continues to show robust activity in preclinical studies.

## Additional Programs and Platform Expansion Activities

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

Our CAR T immunotherapy pipeline include autologous ATA2271 and allogeneic ATA3271 targeting mesothelin, which is a tumor antigen expressed on a number of solid tumors including mesothelioma, ovarian cancer, pancreatic cancer, non-small cell lung cancer and other tumors over-expressing mesothelin. Both programs were licensed to Bayer in December 2020, pursuant to an exclusive, field-limited license (the Bayer License Agreement). In May 2022, Bayer notified us of its decision to terminate the Bayer Agreements and on August 2, 2022, we entered into the Bayer Termination Agreement which returned full product development and commercialization rights for ATA2271 and ATA3271 to us effective July 31, 2022. See section 'Terms of Certain License and Collaboration Agreements' below for additional details.

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

ATA2271 is designed to improve efficacy persistence, and durability of response versus CD28/CD3z-based CARs by using a novel 1XX CAR co-stimulatory signaling domain and cell intrinsic checkpoint inhibition technology with a PD-1 dominant negative receptor (DNR). Data from investigational new drug application (IND) enabling studies for ATA2271 were presented at the American Association for Cancer Research (AACR) Virtual Meeting II in June 2020. These data support the first application of the combination of 1XX co-stimulatory domain and cell intrinsic checkpoint inhibition technology with a PD-1 DNR that are associated with less cell exhaustion, improvements in functional persistence, serial cell killing and in vivo efficacy, which was maintained through multiple tumor re-challenges when compared with first-generation CD28/CD3z-based mesothelin CAR. The FDA accepted the IND application submitted by our collaborators at MSK in August 2020, and in September 2020, MSK initiated an open-label, single-arm Phase 1 clinical study of ATA2271 for patients with advanced mesothelioma. The first preclinical, clinical and translational data from the lowest dose cohorts of this study, demonstrating early safety and persistence of ATA2271, was presented during a mini oral session at the European Society for Medical Oncology (ESMO) Immuno-Oncology Congress in December 2021. MSK has enrolled and dosed the third cohort of this study. In February 2022, MSK notified the FDA of a fatal serious adverse event associated with a patient treated in the third, higher dose cohort in this study. MSK voluntarily paused enrollment of new patients in this study on a temporary basis while additional information regarding this case is gathered and reviewed. In October 2022, MSK communicated their assessment to the FDA, following which enrollment in this study recently resumed after the voluntary pause. In December 2022, the latest findings, including clinical and safety observations, were presented during a session at the ESMO Immuno-Oncology Con

ATA3271 is an off-the-shelf, allogeneic CAR T therapy targeting mesothelin using a PD-1 DNR and 1XX CAR co-stimulatory signaling domain through our EBV T-cell platform. In preclinical data for ATA3271 we observed anti-tumor activity that we believe indicated functional persistence and significant survival benefit, and we found no evidence of allocytotoxicity in vivo, suggesting that allogeneic MSLN-CAR-engineered EBV T cells are a promising approach for the treatment of MSLN-positive cancers. Following termination of the Bayer Agreements, we have paused development of ATA3271.

We are also developing ATA3431, a multi-targeted allogeneic CAR T immunotherapy targeting B-cell malignancies. 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 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 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 and Tessa Therapeutics Pte Ltd., is conducting a Phase 1 study with an allogeneic CD30-CAR EBVST product candidate in relapsed refractory CD30 positive lymphoma.

## Multiple Sclerosis

Competition in the MS market is high with at least 20 therapies, including four generics or bioequivalents, approved in the U.S. and EU for the treatment of various forms of MS, including clinically isolated syndrome, relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS). There are many competitors in the MS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Briumvi (ublituximab), marketed by TG Therapeutics, Ponvory (S1P modulator), marketed by Johnson, and Kesimpta<sup>®</sup> (anti-CD20 monoclonal antibody), marketed by Novartis, were approved in the U.S. and/or EU for the treatment of relapsing forms of MS.

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

## CAR T Program

There are currently six autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel), Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus<sup>TM</sup>(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 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 Territory following regulatory approval. Atara retains full rights to tab-cel in other major markets, including North America, Asia Pacific and Latin America. In September 2022, we entered into Amendment No. 1 to the Pierre Fabre Commercialization Agreement (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 transfer to Pierre Fabre, we will be 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 also 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 HCR Molag Fund L.P (HCRx) for a total investment amount of \$31.0 million, subject to a cap between 185% and 250% of the total investment amount by HCRx.

We are responsible at our cost for the conclusion of the ongoing Phase 3 ALLELE clinical study and the Phase 2 multi-cohort clinical study. We will also be responsible at our cost for certain other activities directed to obtaining regulatory approval for tab-cel for EBV-positive lymphoproliferative disease pursuant to the terms of the Pierre Fabre Commercialization Agreement in Europe. Pierre Fabre will be responsible at its cost for obtaining and maintaining all other regulatory approvals, post-approval obligations and for commercialization and distribution of Ebvallo in the Territory. We will own any intellectual property rights developed solely by us under the Agreement.

Pierre Fabre paid us an upfront cash payment of \$45.0 million for the exclusive license grant 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. Subject to the terms of the HCRx Agreement, 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, 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 2022, we entered into a separate manufacturing and supply agreement with Pierre Fabre for us to manufacture Ebvallo for Pierre Fabre to use in the Territory based on a fixed price through December 31, 2023 and cost plus a margin beginning on January 1, 2024. We are responsible for manufacturing and supplying Pierre Fabre with Ebvallo for commercialization in the Territory at Pierre Fabre's cost for a minimum of seven years from the first commercial sale, as defined in the Pierre Fabre Commercialization Agreement, of Ebvallo in the Territory. Following this period, we have the option to transfer the manufacturing responsibility and related manufacturing technology to a third party CMO, and Pierre Fabre may also elect to directly assume the manufacturing responsibility and receive the related manufacturing technology.

We are also responsible for cell selection services 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. After this period of time, if we agree to continue to provide cell selection services, it shall be at the sole expense of Pierre Fabre.

## Bayer License and Collaboration Agreements

In December 2020, we entered into the Bayer License Agreement to develop mesothelin-directed CAR T-cell therapies for the treatment of solid tumors, pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271 (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 to be responsible for the further development of ATA2271 at its cost. Bayer was responsible for the development of ATA3271 at Bayer's cost, except for certain mutually agreed preclinical, translational, manufacturing and supply chain activities performed by us relating to ATA3271. Bayer was also solely responsible for commercializing the Licensed Products at its cost.

In May 2022, Bayer notified us of its decision to terminate the Bayer Agreements, and on August 2, 2022, we entered into the Bayer Termination Agreement with an effective date of July 31, 2022. Upon the termination effective date, full product development rights related to the Licensed Products 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.

## 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, Atara will retain non-exclusive rights to the licensed products.

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

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 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 license 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 inlicensed 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 33 patent families having a total of more than 330 issued patents or patent applications. Our patents and patent applications (if issued) are expected to expire between 2023 and 2042, 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 sixteen different trademark families comprised of more than 178 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 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 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, 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 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 res

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 suspected adverse reaction over the rate listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to 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 t

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the 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 need

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

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

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan or 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. Pediatric exclusivity is a type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

## 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.

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 within 6 months of the application filing date, compared with 10 months from the filing date for regular applications.

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. 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. A product shown to be biosimilar or interchangeable with an FDA-approved reference biologic which can potentially reduce the cost and time required to obtain approval to market the 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 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, 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 Inflation Reduction Act of 2022 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 Inflation Reduction Act of 2022 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 (GDPR), which imposes obligations and restrictions on the collection and use of personal information relating to individuals located in the EEA (including health information).

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

## Foreign Regulation

In addition to regulations in the U.S., we are subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of our product candidates 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 much like an IND in the U.S., prior to the commencement of human clinical studies. In the EU, for example, in accordance with the requirements of the EU Clinical Trials Regulation 536/2014 (CTR), a CTA must be submitted to the competent national health authority or a single application must be made to the centralized EU Portal, Clinical Trials Information System (CTIS) and to independent ethics committees in each country in which a company intends to conduct clinical studies. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed in that country. In all cases, the clinical studies must be conducted in accordance with GCP and other applicable regulatory requirements. As part of the application process, the sponsor shall propose a reporting Member State, who will coordinate the validation and evaluation of the application. The reporting Member State shall consult and coordinate with the other concerned Member States. If an approval is issued, the sponsor can start the clinical trial in all concerned Member States. However, a concerned Member State can in limited circumstances declare an "opt-out" from an approval. In such a case, the clinical trial cannot be conducted in that Member State. The 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 have been able to, but are not obligated to, use the CTIS starting January 31, 2022. Beginning January 31, 2023, clinical trial sponsors must use the CTIS to apply to start 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

Under EU regulatory systems, a company may submit Marketing Authorization Applications 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 will be evaluated by the Committee for Medicinal Products for Human Use. If this committee delivers a favorable opinion, this typically results in the grant by the European Commission of a single marketing authorization that is valid for all EU member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

Conditional marketing authorization in the 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 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 application for MAA is made. 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

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 that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Outside the U.S., there are additional challenges in ensuring adequate coverage and payment for our products. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory approval for a product and may require us to conduct a clinical study that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of this type of clinical study could be expensive and result in delays 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 that has 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 left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the United Kingdom was subject to a transition period until December 31, 2020 (the Transition Period) during which EU rules continued to apply. A UK-EU Trade and Cooperation Agreement (the Deal) that outlines the future trading relationship between the United Kingdom and the EU was agreed in December 2020 and has been approved by each EU member state and the United Kingdom.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, 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 United Kingdom and the EU. Great Britain (made up of England, Scotland and Wales) is no longer covered by the EEA's procedures for the grant of marketing authorizations (Northern Ireland will be covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures, 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 Marketing Authorization Applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, would delay or prevent us from commercializing our product candidates in the United Kingdom or the EU and restrict our ability to generate revenue and achieve and sustain profitability.

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

Orphan designation in Great Britain following Brexit is granted on an essentially identical basis to in the EU, but is based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that are currently designated as orphan conditions in Great Britain will no longer be 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 involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

## Manufacturing

In 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. Based on our expectations of patients and demand for product in the EU, we believe our current inventory of Ebvallo is sufficient to supply commercial demand in the EU until the end of 2023.

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. There have been 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 the COVID-19 pandemic, including leukapheresis collections, which supply raw materials used for our product candidates. If we are unable to obtain such raw materials or other necessary raw materials in a timely manner, our business operations and manufacturing capabilities could be adversely affected.

In addition to 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 of our product candidates. In February 2023, we amended the CRL MSA to extend the term until the earlier of September 30, 2023 or receipt of certain batches of our product and product candidates.

Our current manufacturing strategy is to evaluate each product candidate and determine which site in our manufacturing network provides the phase-appropriate technical, quality and regulatory compliance requirements. In addition, the long-range supply requirements of our product candidates are evaluated periodically to ensure we are planning manufacturing capacity and capabilities accordingly across our network. Our manufacturing network is comprised of our own facility and the manufacturing capabilities of our partners, including MSK and 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, 2022, we had 334 employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. Our human capital strategy is designed to enable successful execution of our business objectives, while fostering a collaborative and innovative culture, that embraces diversity and inclusion. We monitor our success with insights across human capital metrics such as employee engagement, vacancy rates, time to hire, promotion rates, performance ratings, succession depth, retention, EEO compliance, pay equity, and diversity representation. The principal purposes of our compensation policies and equity incentive plans are to attract, retain and motivate employees and directors by paying for performance through the granting of stock-based compensation awards and cash-based performance bonus awards. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we consider our relations with our employees to be good.

## **COVID-19 Business Update**

We continue to monitor the impact of the COVID-19 pandemic on our business and operations and have taken steps designed to minimize such impacts and maintain business continuity. 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.

Our clinical study and operational teams work with clinical sites to minimize the impact of the COVID-19 pandemic. Where needed, remote study visits, tele-medicine, home health care, and other methods have been leveraged to ensure continuity of care for patients while preserving key endpoint data.

To date, the COVID-19 pandemic has not materially impacted our or our partners' clinical, research and development, regulatory, and manufacturing operations or timelines. However, at the onset of the pandemic, we experienced, and we may again experience, some transient delays in clinical study operations, as a result COVID-19.

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.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that product candidates will fail to prove effective, gain regulatory approval or become commercially viable. We have one product, Ebvallo, which is approved in the EU and have not generated any revenues from commercial product sales, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have incurred significant operating losses in every annual reporting period since our inception. For the year ended December 31, 2022, we reported a net loss of \$228.3 million.

To date, we have not generated any revenue from commercial product sales. We do not know when, or if, we will generate sufficient revenue from commercial product sales 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 no commercial product revenues. We may never generate revenues from the sale of commercial products or achieve profitability.

To date, we have not generated any revenues from commercial product sales. We have regulatory approval for one product, Ebvallo, in the EU. We have outlicensed the commercialization rights to Ebvallo in the EU to Pierre Fabre under the Pierre Fabre Commercialization Agreement and we have sold certain of our royalty and milestone interests under the Pierre Fabre Commercialization Agreement, subject to a specified cap, to HCRx pursuant to the HCRx Agreement. Our ability to generate revenues from product sales and achieve profitability will be subject to the Pierre Fabre 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 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. Except for certain milestone payments payable to us in connection with the approval and transfer of the Ebvallo marketing authorization, we will not receive any meaningful milestones or royalty payments from Pierre Fabre until the applicable royalty caps under the HCRx Agreement are 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 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 as of December 31, 2022, together with the \$40.0 million received in January 2023 for achievement of certain milestones under the Pierre Fabre Commercialization Agreement, will be sufficient to fund our planned operations into the second quarter of 2024. As of December 31, 2022, we had total cash, cash equivalents and short-term investments of \$242.8 million. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We do not have any committed external source of funds other than milestone and royalty payments that we may receive under the Pierre Fabre Commercialization Agreement, subject to the terms of the HCRx Agreement. Except for certain milestone payments payable to us in connection with the approval and transfer of the Ebvallo marketing authorization, we will not receive any meaningful milestone or royalty payments from Pierre Fabre until the applicable royalty caps under the HCRx Agreement are met, if at all. While we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings, through potential collaborations, partnering or other strategic arrangements, or a combination of the foregoing, additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may not have sufficient working capital to fund our operations or be able to continue as a going concern, and we may be required to delay, limit, reduce or terminate preclinical studies or other development activities for one or more of our product candidates.

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

We may seek required additional capital through a variety of means, including through private and public equity offerings and debt financings. For example, in December 2022, we sold certain of our royalty and milestone interests under the 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 the COVID-19 pandemic, rising inflationary pressures, the ongoing Russian invasion of Ukraine 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.

Our announced workforce reduction 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 announced a reduction in workforce by approximately 20% across all areas of our company, including members of management. The reduction in force reflects 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 the 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 reduction 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 Ebvallo in the EU or our product candidates in the future.

## 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 (i) certain transition services to FDB by us and (ii) 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. During the transition period, the Fujifilm Transaction will require significant time and resources from us which may 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 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 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 and product candidates, which could materially harm our business.

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

Our business could be adversely affected by health epidemics and pandemics, including the ongoing COVID-19 pandemic, which has presented a substantial public health and economic challenge around the world and has affected, and continues to affect, our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. As a result of the ongoing COVID-19 pandemic, we transitioned most of our employees to a work-from-home model. We continue to maintain essential in-person manufacturing and laboratory functions in order to advance key research, development and manufacturing priorities. In connection with these measures, we may be subject to claims based upon, arising out of, or related to COVID-19 and our actions and responses thereto, including any determinations that we may make to continue to operate our offices and facilities where permitted by applicable law. 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 the ongoing COVID-19 pandemic or other infectious diseases, could impact our manufacturing capabilities and third party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, standard transportation channels have been impacted and we and other manufacturing, testing, product disposition, CMOs and external testing laboratories are subject to enhanced risk assessment and mitigation measures. In addition, there have been and may continue to be interruptions in the supply of leukapheresis collections, which supply raw materials used in our products.

Our clinical trials may also be affected by health epidemics and have been affected by the ongoing and evolving COVID-19 pandemic. Clinical site initiation and patient enrollment have 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 or as a result of changing practice patterns that impact the diseases our trials address. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services or if patients contract COVID-19 or are forced to quarantine. For example, while most clinical trial sites for our studies, including our Phase 3 clinical trial of tab-cel in patients with EBV+ PTLD, remain open to enrollment for patients, some sites have limited the screening and enrollment of new patients due to governmental orders related to COVID-19, or fear of infection of COVID-19, have limited, and may continue to limit, patients' abilities to access clinical sites. COVID-19-related travel restrictions may also interrupt key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses. At the outset of the COVID-19 pandemic, we observed a

temporary slow-down in stem cell and solid organ transplant volumes, which may have decreased the eligible patient population for the tab-cel Phase 3 study. In April 2020, we initiated a temporary pause in the screening and enrollment of patients in our 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 ongoing COVID-19 pandemic may require 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 COVID-19, may be adversely impacted.

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

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

We only have one product, Ebvallo, that has gained regulatory approval in the EU. Currently, our prioritized clinical-stage product candidates include ATA188 and tabcel in the U.S. 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 has approved the Marketing Authorization Application 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 grants 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 obligatio

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 more information, including additional CMC information, preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. 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. In February 2023, we held a meeting with the FDA on clinical aspects for a potential BLA submission for tab-cel. We expect to hold a near-term meeting to further discuss CMC matters relating to a potential BLA submission for tab-cel, including aspects related to comparability that may support pooling clinical data from different process versions. While we continue to discuss such potential pathways with the FDA to enable filing of a BLA for tab-cel without the need for a new clinical trial, we may not ultimately reach agreement with the FDA on a pathway to BLA submission with the current clinical dataset. In this case, the conduct of an additional clinical trial or trials in the lead indication may be necessary to support a BLA for tab-cel, which would result in considerable delay to a BLA submission or could lead us not to pursue a BLA submission. Conducting a clinical trial 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 s

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 ongoing and evolving 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 riskbased 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 ongoing COVID-19 pandemic. On December 29, 2021, the FDA implemented temporary changes to its inspectional 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 a draft guidance document outlining its policies regarding remote regulatory assessments. We cannot predict whether, and when, FDA will decide to pause or resume inspections due to the COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. 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 without clinical studies.

If we do obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates, such as our novel T-cell product candidates and next-generation CAR T programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EC and FDA for existing 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 existing autologous CAR T therapies. For instance, allogeneic product candidates may result in adverse events not experienced with autologous products. Even if a product candidate was to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn 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.

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 or may utilize in later clinical studies. 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.. Furthermore, modifications to the total sample size of the ALLELE study and the statistical approach may be necessary depending on the FDA's conclusion regarding the comparability of different process versions of tab-cel used in the ALLELE study. Ebvallo was approved under the exceptional circumstances regulatory pathway, therefore continuation of the Ebvallo marketing authorization is subject to annual reassessments. The annual re-assessments 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.

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

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

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

From time to time, we or our partners may announce or share with regulatory 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 ongoing COVID-19 pandemic or other epidemics or pandemics;
- •delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a study design that we are able to execute;

- •delay or failure in obtaining authorization to commence a study or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a study;
- •delay or failure in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- •delay or failure in obtaining institutional review board (IRB) approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical study at each site;
- •withdrawal of clinical study sites from our clinical studies or the ineligibility of a site to participate in our clinical studies;
- •delay or failure in recruiting and enrolling eligible subjects to participate in a study;
- •delay or failure in subjects completing a study or returning for post-treatment follow-up;
- •clinical sites and investigators deviating from study protocol, failing to conduct the study in accordance with regulatory requirements, or dropping out of a study;
- •an FDA or other regulatory authority clinical site inspection reveals serious violations of regulations applicable to clinical investigations, which may result in requests for additional data analyses and/or rejection of data deemed unreliable;
- •inability to identify and maintain a sufficient number of study sites, including because potential study sites may already be engaged in competing clinical study programs enrolling the same population;
- •failure of our third party clinical study managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- ·delay or failure in adding new study sites;
- •interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- •feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol for a study;
- •a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical studies 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 ongoing 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, ATA188 or any other product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies as required by the FDA or other regulatory authorities. We have experienced some transient delays in clinical trial site initiation and patient enrollment in certain of our clinical trials, including our ALLELE study, as a result of the evolving impact of the ongoing 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 nonrenewal 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 tabcel 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 clinics, patient foundations, or our own market research, and may prove to be incorrect. Further, new studies, product approvals or market research may change the estimated incidence or prevalence of these diseases, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect our 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, 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 United Kingdom (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. Both the FDA and the EMA have granted us orphan drug designation for tab-cel for EBV+ PTLD after HCT or SOT.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same biologic for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Furthermore, these periods are expected to be reduced in the EU following the publication of a new applicable legal framework by the EC expected to be published in Q2 2023. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. 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 recent 11<sup>th</sup> Circuit decision. 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 do 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 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 timely 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.

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. In December 2021, ATA188 received fast track designation for treatment of patients with PPMS and SPMS. 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 on 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 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 approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the US, EU, the UK, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished.

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

Even if we, 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 cGTP and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

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

The occurrence of any event or penalty described above may 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, inlicense 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 inlicense or acquire them. Any product candidates we identify, acquire, in-license, or develop 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.

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, 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 the ongoing COVID-19 pandemic, earthquakes and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors. In addition, there have been, and there may continue to be, 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 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 contaminations are 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. 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 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. 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 is complete and commercial production qualification activities are ongoing 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 tabcel, ATA188, any product candidates resulting from our next-generation CAR T programs or any other product candidates, we will need to transition the manufacturing of these materials to a CMO. 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 of these products and product candidates depends on the uninterrupted and efficient operation of these facilities, which could be adversely affected by equipment failures, 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. 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 Ebvallo in the EU and several countries outside 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 Pierre Fabre Commercialization Agreement for Ebvallo in Europe and select emerging markets in the Middle East, Africa, Eastern Europe and Central Asia (Territory) for EBV-positive cancers. As a result, we are entirely dependent on Pierre Fabre for marketing and commercialization, including negotiation of pricing and reimbursement, of Ebvallo in the Territory. Except for certain milestone payments payable to us in connection with the approval and transfer of the Ebvallo marketing

authorization, we will not receive any meaningful milestone or royalty payments from Pierre Fabre until the applicable royalty caps under the HCRx Agreement are met, if at all. Furthermore, the timing and amount of any milestone and royalty payments we may receive under the Pierre Fabre Commercialization Agreement, as well as the commercial success of Ebvallo in the Territory, will depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of Ebvallo by Pierre Fabre in the Territory.

Under the terms of the Pierre Fabre Commercialization Agreement, if we receive the EU marketing authorization for Ebvallo in patients with EBV+ PTLD, we are required to transfer the marketing authorization to Pierre Fabre. Pierre Fabre will be responsible for obtaining all other regulatory approvals in the Territory and maintaining all regulatory approvals in the Territory. 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 Pierre Fabre 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 EU marketing authorization and other regulatory approvals in the Territory 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.

We also depend on Pierre Fabre to comply with all applicable laws relative to the commercialization of Ebvallo in the Territory. The failure of Pierre Fabre to devote sufficient time and effort to the commercialization of Ebvallo; 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 and our obligations under the HCRx Agreement. 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 Pierre Fabre Commercialization Agreement or ancillary agreements, once entered into, could have a material adverse effect on our financial position and our obligations under the HCRx Agreement 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 Ebvallo in the Territory. 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 Pierre Fabre 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 Bayer Agreements pursuant to the Bayer Termination Agreement. As a result, we have assumed responsibility for the further development of ATA2271 and ATA3271 and commercialization of the resulting product, if approved, until we enter into a new strategic collaboration with a new partner for ATA2271 and/or ATA3271.

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 and product candidates.

We hold rights under license agreements with our partners, including MSK, QIMR Berghofer and Moffitt that are important to our business. Our discovery and development platform is built, in part, around patent rights in-licensed from our partners. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment

obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners would materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product 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 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 or product candidates as demonstrated in clinical studies;
- •the clinical indications and patient populations for which the product or product candidate is approved;
- •acceptance by physicians and patients of the drug as a safe and effective treatment;
- •the administrative and logistical burden of treating patients;
- •the 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 or product candidates over alternative treatments;
- •the safety of product or 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 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 sales and marketing efforts and those of our collaborators.

Even if we 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 have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that 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. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third party payors will decide with respect to coverage and reimbursement for our drug products. Our partners' inability to promptly obtain coverage

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

incentives to programs that increase the federal government's comparative effectiveness research and established a new Medicare Part D coverage gap discount program.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect into 2031 unless additional Congressional action is taken (with the exception of a temporary suspension instituted during the COVID-19 pandemic that expired on July 1, 2022). To offset the temporary suspension during the COVID-19 pandemic, in 2030, reductions in Medicare payments will be 2.25% for the first half of the year, and 3% in the second half of the year. 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 Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or repelace certain aspects of the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, eliminating the implementation of certain mandated fees, and increasing the point-of-sale coverage gap discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. 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 Affordable Care Act was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments. While the legal challenge to the Affordable Care Act was pending, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. Most recently, the Inflation Reduction Act extended the provision of enhanced subsidies for individuals

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.

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. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other reforms, 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 discounts obligations on pharmaceutical and biological manufacturers for products covered under Medicare Part D.

There have also been administrative developments in the U.S. related to drug pricing. For example, in response to a July 9, 2021 Executive Order from President Biden that included several prescription drug initiatives, 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. Additionally, 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. Most recently, 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the 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 off-label 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 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  $\geq$ 1 treatment-refractory infection, including EBV, and is conducting two Phase 3 trials for Virus-Associated Hemorrhagic-Cystitis, as well as initiated a Phase 3 trial for the prevention of BKV, CMV, AdV, EBV, HHV06 and JCV in post-allogeneic HSCT patients and Tessa Therapeutics Pte Ltd., is conducting a Phase 1 study with an allogeneic CD30-CAR EBVST product candidate in relapsed refractory CD30 positive lymphoma.

Competition in the MS market is high with at least 20 therapies, including four generics or bioequivalents, approved in the U.S. and EU for the treatment of various forms of MS, including clinically isolated syndrome, relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS). There are many competitors in the MS market, including major multi-national fully-integrated pharmaceutical companies and established biotechnology companies. Most recently, Briumvi (ublituximab), marketed by TG Therapeutics, Ponvory (S1P modulator), marketed by Johnson, and Kesimpta® (anti-CD20 monoclonal antibody), marketed by Novartis, were approved in the U.S. and/or EU for the treatment of relapsing forms of MS.

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

There are currently six autologous CAR T therapies approved in the U.S. and/or EU: Novartis' Kymriah® (tisagenlecleucel), Gilead/Kite's Yescarta® (axicabtagene ciloleucel) and Tecartus<sup>TM</sup>(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 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, they will be priced at a significant premium over competitive generic products. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

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

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover 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 EU due to us from Pierre Fabre under the Pierre Fabre 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 Pierre Fabre Commercialization Agreement. In the event of actual or alleged breaches of the Pierre Fabre 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, 2022, we had 334 employees after excluding those terminated in October 2022 as part of the reduction in force announced in August 2022. We may encounter difficulties in managing the size of our operations to support our continuing development activities and potential commercialization of our product and 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;
- •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, 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, 2020 through December 31, 2022, the reported sale price of our common stock has fluctuated between \$2.83 and \$28.20 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

- •the success of competitive products or technologies;
- •regulatory actions with respect to our product candidates or products or our competitors' product candidates or products;
- •actual or anticipated changes in our growth rate relative to our competitors;

- •announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- •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 has often unrelated to 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 has often unrelated to 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 has often unrelated to the possible repeal and/or replacement of all or portions or in laws and policies governing from 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 has often unrelated to the policies of the Affordable Care Act or c

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 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

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

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

#### **General Risk Factors**

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

We are highly dependent upon our executive officers and other key employees and the loss of the services of any of our executive officers or other key employees, including scientific, technical or management personnel, could impede the achievement of our corporate objectives. In August 2022, we announced a reduction of our workforce by approximately 20% across all areas of our company, including members 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 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 Health Insurance Portability and Accountability Act of 1996 (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 adopted the General Data Protection Regulation (EU) 2016/679 (EU GDPR), in May 2018 which introduced strict requirements for the processing of personal information 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 (the "targeting test") or monitoring of their behavior (the "monitoring test"). As such, the EU GDPR applies to us to the extent we are established in an EU Member State, we are processing personal information in the context of an establishment in an EU Member State or we meet the requirements of either the targeting test or the monitoring test.

The EU GDPR imposes onerous and comprehensive privacy, data protection, and data security obligations onto controllers and processors, 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 supervisory authorities without undue delay (and no later than 72 hours where feasible) and/or concerned individuals; (vi) enhanced requirements for obtaining valid consent from data subjects; (vii) obligations to consider data protection as any new products or services are developed; and (viii) the provisions of more detailed privacy notices for clinical trial subjects and investigators. The EU GDPR also provides that EU Member States may introduce further laws and regulations limiting the processing of genetic, biometric, or health data, which could limit our ability to collect, use and share EU personal information, cause our compliance costs to increase, require us to change our practices, adversely impact our business, and harm our financial condition.

The EU GDPR also restricts the transfer of personal information from the EEA to the United States and other countries that the European Commission does not recognize as having "adequate" data protection laws 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 has 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 (CJEU). 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. Moreover, new versions of the European Commission's Standard Contractual Clauses (new EU SCCs), now the primary safeguard available for the lawful transfer of personal information from the EU to the U.S., were adopted in June 2021, which impose onerous obligations on the contracting parties. These new EU SCCs must be used in all new contracts going forward (where there are restricted transfers of personal information), with existing contracts entered into before September 27, 2021 required to be updated by December 27, 2022. As such,

any transfers by us or our vendors of personal information from the EU may not comply with European data protection law, may increase our exposure to the EU GDPR's heighted sanctions for violations of its cross-border data transfer restrictions, and may reduce demand from companies subject to European data protection laws.

Assisting our customers, partners, and vendors in complying with the EU GDPR, or complying with the EU 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.

On October 7, 2022, the U.S. President introduced an executive order to facilitate a new Trans-Atlantic Data Privacy Framework, which is the new EU-US adequacy mechanism following Privacy Shield. On December 13, 2022, the European Commission also published its draft adequacy decision which stated that the new executive order and Trans-Atlantic Data Privacy Framework is able to meet the concerns raised in Schrems II. If the draft adequacy decision is approved by the European Commission and implemented, the agreement will facilitate the transatlantic flow of personal information and provide additional safeguards to data transfer mechanisms (including EU SCCs and Binding Corporate Rules) for companies transferring personal information from the EU to the U.S. However, before parties rely on the new Trans-Atlantic Data Privacy Framework there are still legislative and regulatory steps that must be undertaken in both the EU and the U.S. The Schrems II decision also led to a requirement for companies to carry out a transfer privacy impact assessment which, among other things, assesses laws governing access to personal information in the recipient country and considers whether supplementary measures that provide privacy protections additional to those under the SCCs will need to be implemented to ensure an "essentially equivalent" level of data protection to that afforded in the EU. Therefore, at present the new EU SCCs are still the primary safeguard available for personal information transfers from the EU to the U.S. As such, the current legal position may have implications for our cross-border data flows and may result in compliance costs.

Complying with the EU 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.

Companies that must comply with the EU 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 or 4% of consolidated global turnover and restrictions or prohibitions on data processing. The EU 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 EU GDPR.

Further, following the United Kingdom's exit from the EU, known as Brexit, the EU GDPR's obligations continue to apply to the United Kingdom in substantially unvaried form under the so called "UK GDPR" by virtue of section 3 of the European Union (Withdrawal) Act 2018. The UK GDPR exists alongside the UK Data Protection Act 2018 which implements certain derogations in the UK GDPR into English law. Under the UK GDPR, companies established in the United Kingdom and companies not established in the United Kingdom but who process personal information in relation to the offering of goods or services to individuals in the United Kingdom, or to the monitoring of their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to the greater of £17.5 million or 4% of consolidated global turnover. As a result, we are potentially exposed to two parallel data protection regimes, each of which authorizes fines and the potential for divergent enforcement actions. It should also be noted that the UK Information Commissioner's Office (ICO) 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 ICO has also published its version of the transfer impact assessment and information guidance on international transfers, although entities may choose to adopt either the EU or UK style transfer impact assessment. In terms of international data transfers between the UK and the U.S., it is understood that the UK and the U.S. are negotiating an adequacy agreement.

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. For example, the California Consumer Privacy Act (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 California Privacy Rights Act (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. Other states, such as Colorado, Connecticut, Utah, and Virginia, have already passed similar comprehensive privacy laws that have or will also go into effect in 2023, and several more are considering their own versions of privacy 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.

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 are potentially vulnerable to breakdown, service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third party vendors, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our system infrastructure, or that of our third party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through accidental actions or omissions by trusted insiders, cyber attacks or cyber intrusions, including by computer hackers, viruses, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Additionally, the increased usage of computers operated on home networks due to the shelter-in-place or similar restrictions related to the COVID-19 pandemic may make our systems more susceptible to security breaches. 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. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

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

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to \$250,000 per violation and/or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one-year imprisonment. The criminal

penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm

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

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

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. legislations 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, 2022, we had significant U.S. federal and state NOLs due to prior period losses. Under the Tax Cuts and Jobs Act (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. The CARES Act temporarily suspended this 80% taxable income limitation, allowing an NOL carryforward to fully offset taxable income in tax years beginning before January 1, 2021 which had no impact on our financial statements. It remains uncertain if, and to what extent, various states will conform to the Tax Act or the CARES Act. Neither the Tax Act nor the CARES Act had 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, 2022 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 prechange 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 Thousand Oaks, 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 and product candidates. Our ability to obtain clinical supplies of our product and product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, including, for example, the ongoing COVID-19 pandemic.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

Our corporate headquarters are located in 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. 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 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 pre-clinical 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 January 31, 2023, there were 5 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

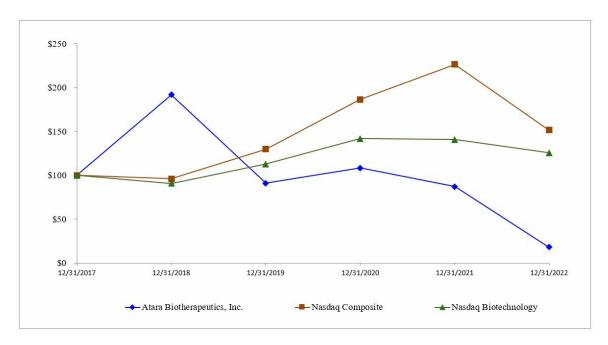
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

#### **Stock Performance Graph**

The following graph compares the cumulative total return on an indexed basis of a \$100 investment, made at the beginning of the five-year period ended December 31, 2022, in the Company's common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index.

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

# COMPARISON OF FIVE-YEAR CUMULATIVE TOTAL RETURN



As of December 31,	Atara Biotherapeutics, Inc.	Nasdaq Composite	Nasdaq Biotechnology
2017	100.00	100.00	100.00
2018	191.93	96.12	90.68
2019	90.99	129.97	112.81
2020	108.45	186.69	141.78
2021	87.07	226.63	140.88
2022	18.12	151.61	125.52

# Item 6. [Reserved]

Not Required.

#### 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) for commercial sale in the European Union (EU) by the European Commission (EC) under the proprietary name Ebvallo<sup>TM</sup>. We are the most advanced allogeneic T-cell immunotherapy company and intend to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-driven diseases or other serious diseases through incorporation of engineered chimeric antigen receptors (CARs) or T-cell receptors (TCRs). Atara is applying this one platform, that does not require TCR or HLA gene editing, to create a robust pipeline. Our strategic priorities are:

- Tab-cel®: Atara's most advanced T-cell immunotherapy program, tab-cel, has received MAA for commercial sale in the EU under the proprietary name Ebvallo and is partnered with Pierre Fabre Medicament (Pierre Fabre) for commercialization in Europe and potential commercialization, if approved, in select emerging markets. Tab-cel (tabelecleucel) is currently in Phase 3 development in the U.S. for patients with EBV-driven post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed rituximab or rituximab plus chemotherapy, as well as other EBV-driven diseases;
- •ATA188: T-cell immunotherapy targeting EBV antigens, believed to be important for the potential treatment of primary and secondary progressive multiple sclerosis, and is currently in Phase 2 development; and
- •ATA3219: Allogeneic CAR T targeting CD19, currently in preclinical development, and being developed as a potential best-in-class product intended to target B-cell malignancies, 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 clinical and preclinical programs, including ATA2271, an autologous CAR T immunotherapy currently in Phase 1 development targeting solid tumors expressing the tumor antigen mesothelin; and ATA3271, an allogeneic CAR T immunotherapy currently in preclinical development targeting mesothelin.

Our T-cell immunotherapy platform includes the capability to progress both allogeneic and autologous programs and is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. For our allogeneic programs, we select the appropriate set of cells for use based on a patient's unique immune profile. One of our contract manufacturing organizations (CMOs) has completed commercial production qualification activities for tab-cel and our other CMOs are currently in the process of completing commercial production qualification activities for tab-cel while we build inventory according to our 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 following regulatory approval. We retain full rights to tab-cel in other major markets, including North America, Asia Pacific and Latin America. 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 to receive an additional \$30 million milestone payment from Pierre Fabre following European Commission (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 Territory, and (ii) the supply price mark up on Ebvallo purchased by Pierre Fabre. Additionally, we also 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 HCR Molag Fund L.P (HCRx) for a total investment amount of \$31.0 million, subject to a cap between 185% and 250% of the total investment amount by HCRx.

In December 2020, we entered into a Research, Development and License Agreement with Bayer (the Bayer License Agreement) pursuant to which we granted to Bayer an exclusive, field-limited license under the applicable patents and know-how owned or controlled by us and our affiliates covering or related to ATA2271 and ATA3271. In March 2021, as contemplated by the Bayer License Agreement, we entered into (i) a Manufacturing and Supply Agreement (Bayer Manufacturing Agreement); (ii) a Pharmacovigilance Agreement; (iii) a Quality Agreement; and (iv) a Technology Transfer Agreement, in each case, with Bayer, to further advance our collaboration with Bayer. 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 (Bayer Termination Agreement) with Bayer that terminated the Bayer Agreements and returned full product development rights for ATA2271 and ATA3271 to Atara effective as of July 31, 2022.

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

Our research facilities in Thousand Oaks, California (ARC) and Aurora, Colorado contain our translational and pre-clinical 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, at which time we assigned the lease for the ATOM Facility to FDB in connection with the closing of the Fujifilm Transaction. We also entered into a Master Services and Supply Agreement with FDB (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 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. Based on our expectations of patients and demand for product in the EU, we believe our current inventory of Ebvallo is sufficient to supply commercial demand in the EU until the end of 2023.

We also work with Charles River Laboratories (CRL) pursuant to the Commercial Manufacturing Services Agreement that we entered into in December 2019 (CRL MSA). Pursuant to the CRL MSA, CRL provides manufacturing services for our product and certain of our product candidates. In February 2023, we amended the CRL MSA to extend the term until the earlier of September 30, 2023 or receipt of certain batches of our product and product candidates.

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 August 2022, we announced a reduction in workforce of approximately 20% of total workforce to focus our activities as a leaner organization centered on research and development to further advance our innovative pipeline, while reducing cash burn. The workforce reduction is expected to include total restructuring charges of approximately \$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 Act and continuing health care coverage over 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 will be paid between October 2022 and November 2023. All of the severance costs represent cash expenditures. In connection with the reduction in workforce, we expect to realize reductions in annualized operating expenses of approximately \$25.0 million by fiscal 2023 due to lower compensation-related costs.

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 otherwise payable by Pierre Fabre to us under the Pierre Fabre Commercialization Agreement. The total royalties and milestones payable to HCRx under the HCRx Agreement are capped between 185% and 250% of the total investment amount by HCRx, dependent upon the timing of such royalties and milestones.

#### **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 \$228.3 million, \$340.1 million and \$306.6 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of \$1.7 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, 2022, our cash, cash equivalents and short-term investments totaled \$242.8 million, which we intend to use to fund our operations.

#### Revenues

We have never generated revenues from the commercial sale of products and have incurred losses since inception. Our revenues to date are derived solely from agreements with Bayer and Pierre Fabre, primarily related to upfront license fees, fees for research, process development and translational activities and technology transfer fees.

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

#### Research and Development Expenses

The largest component of our total operating expenses since inception has been our investment in research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development 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 development of ATA188 in PMS;
- •continuing to develop product candidates based on our next-generation CAR T programs;
- •continuing to develop our product candidates in additional indications, including tab-cel for EBV+ cancers;
- •continuing to develop other preclinical product candidates; and
- •leveraging our relationships and experience to in-license or acquire additional product candidates or technologies.

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

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

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

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

#### General and Administrative Expenses

General and administrative expenses consist primarily of compensation and benefits for legal, human resources, finance, commercial and other general and administrative employees, including stock-based compensation; professional services costs, including legal, patent, human resources, audit and accounting services; other outside services and consulting costs; 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 and Other Income, net

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

#### 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, 2022, 2021, and 2020.

#### 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. Due to the early stage of our licensed technology, the license of such technology is typically combined with the additional promises in these agreements as one combined 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, 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 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 do not expect will be recognized in the next 12 months. This estimate is based on our forecasted patient demand and current operating plan and, if patient demand or our operating plan should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

#### Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate and accrue expenses, the largest of which is related to research and development expenses, including those related to clinical studies and 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 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 expense and amortized over the service period as the services are provided.

For the years ended December 31, 2022 and 2021, there were no material changes from our estimates of accrued research and development expenses. We do not believe there is a reasonable likelihood that there will be a material change in the future estimates of accrued research and development expenses. However, if actual results are not consistent with our estimates, we may be exposed to changes in accrued research and development expenses that could be material or the accrued research and development expenses reported in our financial statements may not be representative of the actual economic cost of accrued research and development.

#### Stock-based Compensation

We have stock-based compensation programs, which include restricted stock units (RSUs); stock options and an employee stock purchase plan. See Note 2 — "Summary of Significant Accounting Policies" and Note 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 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 Prior to 2021, expected volatility was estimated using comparable public companies' volatility for similar terms. Beginning in 2021, volatility is estimated using an average of Atara's historical volatility and comparable public companies' volatility for similar terms.
- •Expected dividend rate We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore, we have assumed an expected dividend yield of 0%.
- •Risk-free interest rate The risk-free interest rate is based on the yields of U.S. Treasury securities with expected terms similar to that of the associated award.
- •The fair value of our common stock is 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 Atara's income tax expense, as well as the temporary differences that exist as of December 31, 2022.

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

all or some portion of the deferred tax assets may not be realized. If appropriate, a valuation allowance is recorded against deferred tax assets to offset future tax benefits that may not be realized.

We do not believe that there is a reasonable likelihood that there will be a material change in our liability for uncertain income tax positions or our effective income tax rate. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to losses that could be material. Atara recorded a valuation allowance of approximately \$422.5 million as of December 31, 2022 related primarily to net operating loss carryforwards, capitalized research expenses, tax credit carryforwards and stock-based compensation.

#### **Results of Operations**

#### Comparison of the Years Ended December 31, 2022, 2021 and 2020

License and collaboration revenue

License and collaboration revenues for the periods indicated were as follows:

	Year	Year ended December 31,				
				2022	2021	
	2022	2021	2020	compared to 2021	compared to 2020	
			(in thousands)			
License and collaboration revenues	\$ 63,573	\$ 20,340	\$ —	\$ 43,233	\$ 20,340	

License and collaboration revenues were \$63.6 million in 2022 as compared to \$20.3 million in 2021 and no revenue in 2020. The increase in 2022 was primarily due to the termination of the Bayer Agreements, which resulted in the recognition of the remaining deferred revenue related to the Bayer Agreements in the second quarter of 2022. We anticipate that license and collaboration revenues will decrease substantially in future quarters due to the termination of the Bayer Agreements.

#### Research and development expenses

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

	Year ended December 31,				Increase (Decrease)					
		2022		2021	(in t	2020 housands)	202	22 compared to 2021		1 compared to 2020
					(111 t					(11,110)
Tab-cel expenses	\$	40,597	\$	50,086	\$	61,196	\$	(9,489)	\$	(11,110)
ATA188, CAR T and other program expenses		45,597		36,424		25,124		9,173		11,300
Employee and overhead expenses		186,339		195,491		158,330		(9,152)		37,161
Total research and development expenses	\$	272,533	\$	282,001	\$	244,650	\$	(9,468)	\$	37,351

Tab-cel expenses were \$40.6 million in 2022 as compared to \$50.1 million in 2021 and \$61.2 million in 2020. The decrease in 2022 was due to a decrease in clinical trial and EU tab-cel filing and approval activities. The decrease in 2021 was primarily due to higher production activities in 2020 related to the build-up of our tab-cel and process performance qualification activities at our manufacturing facility.

ATA188, CAR T and other program expenses were \$45.6 million in 2022 as compared to \$36.4 million in 2021 and \$25.1 million in 2020. The increase in 2022 was driven by higher ATA188 clinical trial and clinical supply cost and ATA3219 manufacturing activities for IND filing; partially offset by ATA188 Phase 2 initiation milestones for QIMR and CAR T-related license fees for MSK recorded in the 2021 period as well as decrease in ATA3271 IND-enabling activities after program pause. The increase in 2021 was primarily related to research, development, and clinical trial costs related to the enrollment and further advancement of our ATA188 Phase 2 EMBOLD study.

Employee and overhead expenses were \$186.3 million in 2022 as compared to \$195.5 million in 2021 and \$158.3 million in 2020. The 2022 decrease was primarily due to lower compensation-related costs and lower facility-related costs driven by the sale of the ATOM facility; partially offset by the cost of FDB's manufacturing services. In 2022 as compared to 2021, payroll and related costs decreased by \$9.3 million, facility-related costs decreased by \$3.6 million, and outside service costs increased by \$3.7 million. The 2021 increase was primarily due to higher compensation-related costs from increased headcount and higher facility-related costs in support of our continuing expansion of research and development activities. In 2021 as compared to 2020, payroll and related costs increased by \$19.3 million, facility-related costs increased by \$11.7 million, and outside service costs increased by \$6.2 million.

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

#### General and administrative expenses

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

	Y	ear en	ded December 3	31,			(Decrease)	Incre	ease
	2022		2021	(in	2020 thousands)	202	22 compared to 2021	202	to 2020
General and administrative expenses	\$ 71,553	\$	78,801	\$	64,402	\$	(7,248)	\$	14,399

General and administrative expenses were \$71.6 million in 2022 as compared to \$78.8 million in 2021 and \$64.4 million in 2020. The decrease in 2022 was primarily driven by a reduction in US tab-cel commercial activities. The increase in 2021 was primarily due to higher compensation-related costs from increased headcount and activities to support our anticipated launch of Ebvallo in the EU and the commercialization of tab-cel in the U.S.

Total general and administrative expenses for all periods presented were not significantly impacted as a result of the COVID-19 pandemic.

#### 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 Pierre Fabre 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 February 2020 (2020 ATM Facility) and in November 2021 (2021 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. 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, 2022, we sold an aggregate of 1,618,672 shares of common stock under the 2021 ATM Facility, 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.

As of December 31, 2022, we have fully utilized the 2020 ATM Facility and we had \$55.9 million of common stock remaining and available to be sold under the 2021 ATM Facility.

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

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

We have incurred losses and negative cash flows from operations in each year since inception and have not yet begun to generate commercialization revenues from the December 2022 EU approval of Ebvallo. 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, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of

our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings including by utilizing the 2021 ATM Facility, through potential commercialization, 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 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.

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

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

	Dec	December 31,		December 31,
		2022		2021
		(in thou	sands)	
Cash and cash equivalents	\$	92,942	\$	106,084
Short-term investments		149,877		264,984
Total cash, cash equivalents and short-term investments	\$	242,819	\$	371,068

#### 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. The initial term of this lease expires in April 2024. In February 2021, we further amended this lease to add an additional 2,861 square feet of lab space. The contractual obligations during the lease term are not material. We have the option to extend this lease for two additional five-year periods after the initial term.

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

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

	Year Ended December 31,					
	2022		2021	2020		
		(i	n thousands)			
Net cash (used in) provided by:						
Operating activities	\$ (270,430)	\$	(220,522) \$	(180,759)		
Investing activities	202,956		22,258	(120,728)		
Financing activities	53,084		103,944	427,574		
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ (14,390)	\$	(94,320) \$	126,087		

## Operating activities

Net cash used in operating activities was \$270.4 million in 2022 as compared to \$220.5 million in 2021. The increase of \$49.9 million was primarily due to the \$45 million upfront fee received from Pierre Fabre in 2021, with no similar cash flows received in 2022, with the remaining variance due to a reduction in net working capital.

Net cash used in operating activities was \$220.5 million in 2021 as compared to \$180.8 million in 2020. The increase of \$39.7 million was primarily due to an increase in net loss of \$33.5 million and increased usage of net working capital, partially offset by \$45.0 million received as a result of the Pierre Fabre Commercialization Agreement.

#### Investing activities

Net cash provided by investing activities in 2022 consisted of \$293.0 million received from maturities and sales of available-for-sale securities and \$94.8 million in net proceeds received from the sale of the ATOM Facility, partially offset by \$180.6 million used to purchase available-for-sale securities and \$4.2 million in purchases of property and equipment.

Net cash provided by investing activities in 2021 consisted primarily of \$334.0 million received from maturities and sales of available-for-sale securities, partially offset by \$301.1 million used to purchase available-for-sale securities and \$10.6 million in purchases of property and equipment.

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

#### Financing activities

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

Net cash provided by financing activities in 2021 consisted primarily of \$98.7 million of net proceeds from ATM facilities and \$6.8 million of net proceeds from employee stock award transactions, partially offset by \$1.2 million of taxes paid related to the net share settlement of RSUs.

Net cash provided by financing activities in 2020 consisted primarily of \$353.8 million of aggregate net proceeds received from the two underwritten public offerings of common stock and pre-funded warrants, \$69.2 million of net proceeds from ATM facilities and \$6.7 million of net proceeds from employee stock award transactions, partially offset by \$1.5 million of taxes paid related to the net share settlement of RSUs.

#### **Operating Capital Requirements and Plan of Operations**

To date, we have not generated any revenue from commercial product sales. We do not know when, or if, we will generate sufficient revenue from commercial product sales 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.

We expect that existing cash, cash equivalents and short-term investments as of December 31, 2022, together with the \$40.0 million received in January 2023 for achievement of certain milestones under the Pierre Fabre Commercialization Agreement, will be sufficient to fund our planned operations into the second quarter of 2024. 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. In addition, we expect to continue to opportunistically seek access to additional funds through additional public or private equity offerings or debt financings, through potential commercialization, collaboration, partnering or other strategic arrangements, or a combination of the foregoing.

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

- •the timing, costs and results of our ongoing and planned clinical and preclinical studies for our product candidates;
- •our success in establishing and maintaining commercial 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 the Pierre Fabre Commercialization 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, 2022, we had total cash, cash equivalents and short-term investments of \$242.8 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**

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#### Report of Independent Registered Public Accounting Firm

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

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Atara Biotherapeutics, Inc. and subsidiaries (the "Company" or "Atara") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 8, 2023, expressed an unqualified opinion on the Company's internal control over financial reporting.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### **Critical Audit Matters**

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

#### License and Collaboration 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 Bayer and Pierre Fabre.

During 2020 and 2021, the Company entered into a Research, Development and License agreement, a Technology Transfer Agreement, and a Manufacturing and Supply Agreement with Bayer AG ("Bayer").

In 2022, the Company entered into a Termination Agreement with Bayer pursuant to which all existing agreements were terminated. Under the terms of this agreement, full product development and commercialization rights related to ATA2271 and ATA3271 reverted to Atara, and Bayer made an additional payment to Atara for certain activities performed by the Company prior to the termination effective date.

Additionally, 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 therapies and will be responsible for manufacturing and supplying the therapies 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"). Under the terms of the PF Amendment, Atara is 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.

The Company recognizes revenue on out-license agreements as they satisfy their performance obligations and when a customer obtains control of the promised goods or services. As of December 31, 2022, the Company recognized \$63.6 million of revenue under the out-license agreements and deferred revenue amounted to \$85.0 million, of which \$8.0 million is included in current liabilities and \$77.0 million is included in long-term liabilities.

We identified accounting for the out-license 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 an out-license agreement, the method to estimate and measure the progress toward the completion of the performance obligation and the estimated contractual term over which the performance obligation would be completed, auditing such judgments and estimates required extensive audit effort due to the complexity of the out-license 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 and assessing management's method for measuring progress included the following, among others:

- •We tested the operating effectiveness of controls over out-license related revenue, including those related to the evaluation of contract modifications 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 agreement is 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:
  - oPerforming 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.
  - oComparing costs incurred for activities completed to date to the costs forecasted for those activities.
  - oComparing material rights accumulated and earned for activities completed to date to the fulfilment of performance obligations forecasted for those activities.
  - oTesting 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.

#### Accrued Research and Development Expenses & Prepaid Research and Development Expenses - Refer to Note 2 to the financial statements

Critical Audit Matter Description

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

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

Given the number of ongoing research and development activities and the subjectivity involved in estimating related accrued and prepaid expenses, auditing the accrued and prepaid research and development expenses involved especially subjective judgment.

How the Critical Audit Matter Was Addressed in the Audit

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

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

/s/ DELOITTE & TOUCHE LLP

San Francisco, California February 8, 2023

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

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

	I	December 31, 2022	December 31, 2021	
Assets				
Current assets:				
Cash and cash equivalents	\$	92,942	\$ 106,0	84
Short-term investments		149,877	264,9	84
Restricted cash		146	1	94
Accounts receivable		40,221	9	86
Inventories		1,586		_
Other current assets		10,308	12,3	73
Total current assets		295,080	384,6	21
Property and equipment, net		6,300	53,7	80
Operating lease assets		68,022	26,1	59
Restricted cash - long-term		_	1,2	00
Other assets		7,018	2,3	67
Total assets	\$	376,420	\$ 468,1	27
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	6,871	\$ 17,3	68
Accrued compensation		17,659	25,1	
Accrued research and development expenses		24,992	13,4	
Deferred revenue		8,000	40,7	
Other current liabilities		21,394	9,0	
Total current liabilities		78,916	105,7	
Deferred revenue - long-term		77,000	55,7	
Operating lease liabilities - long-term		58,064	25,5	
Liability related to the sale of future revenues - long-term		30,236	ĺ,	
Other long-term liabilities		5,564	1,5	01
Total liabilities		249,780	188,5	
Commitments and contingencies (Note 10)				
Stockholders' equity:				
Common stock—\$0.0001 par value, 500,000 shares authorized as of December 31, 2022 and 2021, respectively; 95,927 and 91,671 shares issued and outstanding as of December 31, 2022 and 2021, respectively		10		9
Additional paid-in capital		1,821,721	1,744,6	
Accumulated other comprehensive (loss) income		(2,067)		68)
Accumulated deficit		(1,693,024)	(1,464,7	
Total stockholders' equity		126,640	279,6	
Total liabilities and stockholders' equity	\$	376,420	\$ 468,1	

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

	2022	2021		2020
License and collaboration revenue	\$ 63,573	\$ 20,340	\$	_
Operating expenses:				
Research and development	272,533	282,001		244,650
General and administrative	71,553	78,801		64,402
Total operating expenses	344,086	360,802		309,052
Loss from operations	(280,513)	(340,462)		(309,052)
Other income (expense), net:				
Gain on sale of ATOM Facility (See Note 7)	50,237	_		_
Interest and other income (expense), net	1,986	367		2,447
Total other income (expense), net	52,223	367		2,447
Loss before provision for income taxes	(228,290)	(340,095)		(306,605)
Provision for income taxes	12	46		15
Net loss	\$ (228,302)	\$ (340,141)	\$	(306,620)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on available-for-sale securities	(1,699)	(664)		76
Comprehensive loss	\$ (230,001)	\$ (340,805)	\$	(306,544)
Basic and diluted net loss per common share	\$ (2.24)	 (3.63)		(4.15)
Basic and diluted weighted-average shares outstanding	 101,990	 93,670		73,973

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

		nmon tock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount		Capital	(Loss) Income	Deficit	Equity
Balance as of January 1, 2020	56,806		6		220 \$	(817,961) \$	290,781
Issuance of common stock and pre-funded warrants through underwritten offering, net of offering costs of \$583	20,060		2	353,586	_	_	353,588
Issuance of common stock through ATM facilities, net of commissions and offering costs of \$1,887	4,786	_		68,004	_	_	68,004
Exercise of pre-funded warrants	57	-	_	_	_	_	
RSU settlements, net of shares withheld	1,112	-	_	(1,521)	_	_	(1,521)
Issuance of common stock pursuant to employee stock awards	551	-	_	6,680	_	_	6,680
Stock-based compensation expense	_	-	_	51,351	_	_	51,351
Net loss	_	_	_	_	_	(306,620)	(306,620)
Unrealized gain on available-for-sale securities	_	-	_	_	76	_	76
Balance as of December 31, 2020	83,372		8	1,586,616	296	(1,124,581)	462,339
Issuance of common stock through ATM facilities, net of commissions and offering costs of \$2,501	6,241		1	98,696	_	_	98,697
RSU settlements, net of shares withheld	1,492	-		(1,244)	_	_	(1,244)
Issuance of common stock pursuant to employee stock awards	566	-	_	6,762	_	_	6,762
Stock-based compensation expense	_	-	_	53,865	_	_	53,865
Net loss	_	-	_	_	_	(340,141)	(340,141)
Unrealized loss on available-for-sale securities	_	_	_	_	(664)	_	(664)
Balance as of December 31, 2021	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 loss on available-for-sale securities	_	-	_	=	(1,699)		(1,699)
Balance as of December 31, 2022	95,927	\$ 1	0	\$ 1,821,721 \$	(2,067) \$	(1,693,024) \$	126,640

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

		Year Ended December 31,					
		2022		2021		2020	
Operating activities							
Net loss	\$	(228,302)	\$	(340,141)	\$	(306,620)	
Adjustments to reconcile net loss to net cash used in operating activities:							
Gain on sale of ATOM Facility		(50,237)		_		_	
Stock-based compensation expense		53,838		53,865		51,351	
Depreciation and amortization expense		5,653		9,345		8,332	
Non-cash operating lease expense		8,915		1,948		1,457	
Amortization of investment premiums		1,024		1,769		828	
Other non-cash items, net		147		108		208	
Changes in operating assets and liabilities:							
Accounts receivable		(39,235)		264		(1,250)	
Inventories		(1,586)		_		_	
Other current assets		1,836		8,182		(8,666)	
Operating lease assets		_		_		886	
Other assets		(266)		(1,727)		(219)	
Accounts payable		(9,211)		9,067		(815)	
Accrued compensation		(7,491)		4,692		5,752	
Accrued research and development expenses		11,541		(2,362)		7,472	
Other current liabilities		2,067		1,618		(187)	
Deferred revenue		(11,468)		35,218		61,250	
Operating lease liabilities		(8,009)		(1,859)		(1,316)	
Other long-term liabilities		354		(509)		778	
Net cash used in operating activities		(270,430)		(220,522)		(180,759)	
Investing activities							
Purchases of short-term investments		(180,589)		(301,129)		(425,868)	
Proceeds from maturities and sales of short-term investments		292,973		333,967		309,653	
Purchases of property and equipment		(4,193)		(10,580)		(4,513)	
Net proceeds from sale of ATOM Facility		94,765		_		_	
Net cash provided by (used in) investing activities		202,956		22,258		(120,728)	
Financing activities							
Proceeds from sale of common stock and pre-funded warrants in underwritten offerings, net		_		_		353,780	
Proceeds from issuance of common stock through ATM facilities, net		21,891		98,697		69,189	
Proceeds from employee stock awards		1,921		6,762		6,680	
Proceeds from sale of future revenues, net		30,605		_		_	
Taxes paid related to net share settlement of restricted stock units		(623 )		(1,244)		(1,521)	
Principal payments on finance lease obligations		(518)		(254)		(389)	
Other financing activities, net		(192)		(17)		(165)	
Net cash provided by financing activities		53,084		103,944		427,574	
Increase (decrease) in cash, cash equivalents and restricted cash		(14,390)		(94,320)		126,087	
Cash, cash equivalents and restricted cash at beginning of period		107,478		201,798		75,711	
Cash, cash equivalents and restricted cash at end of period	\$	93,088	\$	107,478	\$	201,798	
Non-cash investing and financing activities							
Property and equipment purchases included in accounts payable and other accrued liabilities	\$	61	\$	2,139	\$	326	
Accrued costs related to underwritten public offering	\$		\$		\$	192	
Accrued costs related to ATM facility	\$	_	\$	87	\$		
·	\$	332	\$		\$		
Accrued transaction costs related to sale of future revenues	Ψ	332	Ψ		Ψ		
Supplemental cash flow disclosure	\$	335	\$	32	\$	62	
Cash paid for interest	\$	19	\$	15	\$	10	
Cash paid for income taxes	2	19	\$	15	Þ	10	

# ATARA BIOTHERAPEUTICS, INC. Notes to Consolidated Financial Statements

#### 1.Description of Business

Atara Biotherapeutics, Inc. ("Atara", "we", "our" or "the Company") was incorporated in August 2012 in Delaware. Atara is a 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 by the European Commission ("EC") for commercial sale and use in the European Union ("EU") and 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 tab-cel in Europe and select emerging markets in the Middle East, Africa, Eastern Europe and Central Asia (the "Territory"), following regulatory approval. We retain full rights to tab-cel in other major markets, including North America, Asia Pacific and Latin America. See Note 5 for further information.

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. In March 2021, as contemplated under the Bayer License Agreement and to further advance our collaboration, we entered into (i) a Manufacturing and Supply Agreement; (ii) a Pharmacovigilance Agreement; (iii) a Quality Agreement; and (iv) a Technology Transfer Agreement (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 Bayer which terminated the Bayer Agreements (the "Bayer Termination Agreement") and returned full product development and commercialization rights related to ATA2271 and ATA3271 to us, effective as of July 31, 2022. See Note 5 for further information.

We have licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center ("MSK"), rights related to our next-generation CAR T programs from MSK and from H. Lee Moffitt Cancer Center ("Moffitt"), and rights to know-how and technology from the Council of the Queensland Institute of Medical Research ("QIMR Berghofer"). See Note 10 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 Notes 7, 8, and 10 for further information.

In August 2022, we announced a reduction in force that reduced our workforce by approximately 20%. We expect to recognize restructuring charges of \$6.0 million in total for severance and related benefits for employees laid off under the reduction in force. These charges are primarily 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 Cash Flows and 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.

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 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. We expect that existing cash, cash equivalents and short-term investments as of December 31, 2022, together with the \$40.0 million received in January 2023 for achievement of certain milestones under the Pierre Fabre Commercialization Agreement, will be sufficient to fund our planned operations for at least the next twelve months from the date of issuance of these financial statements. However, the uncertainties inherent in Atara's future operations and in our ability to obtain additional funding may raise substantial doubt about our ability to continue as a going concern in future reporting periods. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. 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 additional funding on terms acceptable to us, if at all. 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.

#### Concentration of Credit Risk and Other Uncertainties

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

#### **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, 2022 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 both recorded to interest and other income (expense), net in the consolidated statements of operations and comprehensive loss.

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

#### Fair Value Measurement

The carrying amounts of certain of our financial instruments including cash equivalents, accounts receivable, 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 as of 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. Finished goods inventories in excess of one year of forecasted sales are classified in the Consolidated Balance Sheets as non-current "Other assets."

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. There have been no write-downs of our inventories for the periods presented.

# 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, the Company records period-to-period changes in the ARO liability resulting from the passage of time and revisions to either the timing or the amount of the original estimate of undiscounted cash flows. The Company derecognizes ARO liabilities when the related obligations are settled.

#### 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.

#### **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 expense and amortized over the period in which 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 will 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 of December 31, 2022, our deferred revenue is related to the Pierre Fabre Commercialization Agreement, which is within the scope of ASC 606. As discussed in further detail in Note 5, the terms of these arrangements 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; and royalties on the net sales of licensed products. These payments relate to promised goods or services for which revenue will be recognized upon our satisfaction of the underlying performance obligations.

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

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 any royalty revenue resulting from our out-licensing agreements.

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

#### 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 ("RSAs"), grants of restricted stock units ("RSUs"), and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant. The fair value 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 – Prior to 2021, expected volatility was estimated using comparable public companies' volatility for similar terms. Beginning in 2021, volatility is estimated using an average of Atara's historical volatility and comparable public companies' volatility for similar terms.

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

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

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, 2022, 2021, and 2020 we recorded matching contributions of approximately \$2.3 million, \$2.6 million, and \$2.1 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, 2022 and 2021. 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 recent ASU issued by the Financial Accounting Standards Board ("FASB"). Based on our assessment, the ASUs were determined to be either not applicable or are expected to have minimal impact on our consolidated financial statements.

#### 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,					
	2022	2021	2020			
Unvested RSUs	6,698,858	5,253,347	2,868,407			
Vested and unvested options	10,336,634	9,200,337	7,832,386			
ESPP share purchase rights	86,782	27,238	26,349			
Total	17,122,274	14,480,922	10,727,142			

#### 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:

		Total Amortized		Total Unrealized		Total Unrealized		Total Estimated	
As of December 31, 2022:	Input Level	Cost		Gain		Loss		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

				Total Unrealized	Total Unrealized		Total Estimated	
As of December 31, 2021:	Input Level	Cost		Gain	Los			ir Value
				(in thous				
Money market funds	Level 1	\$ 89,738	\$	_	\$	_	\$	89,738
U.S. Treasury obligations	Level 2	111,832		1		(138)		111,695
Government agency obligations	Level 2	21,346		_		(23)		21,323
Corporate debt obligations	Level 2	99,757		6		(190)		99,573
Commercial paper	Level 2	36,993		_		_		36,993
Asset-backed securities	Level 2	10,174		1		(25)		10,150
Total available-for-sale securities		369,840		8		(376)		369,472
Less: amounts classified as cash equivalents		(104,488)		_		_		(104,488)
Amounts classified as short-term investments		\$ 265,352	\$	8	\$	(376)	\$	264,984

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

		As of Decem	022	As of December 31, 2021					
	A	mortized	E	Stimated	Amortized		Estimated		
		Cost	F	air Value		Cost	Fair Value		
		(in thou		(in thousands)					
Maturing within one year	\$	202,323	\$	201,359	\$	278,457	\$	278,354	
Maturing in one to five years		36,746		35,643		91,383		91,118	
Total available-for-sale securities	\$	239,069	\$	237,002	\$	369,840	\$	369,472	

We considered the current and expected future global economic and market conditions, including the COVID-19 pandemic and the war in Ukraine, and determined that our investments have not been significantly impacted. As of December 31, 2022, 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, 2022, 2021 and 2020, 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, 2022 and 2021, accrued interest receivable was \$0.8 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, 2022, 2021 and 2020.

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, 2022		cember 31, 2021
	(in thou	ısands	s)
Cash and cash equivalents	\$ 92,942	\$	106,084
Restricted cash - short-term	146		194
Restricted cash - long-term	_		1,200
Total cash, cash equivalents and restricted cash	\$ 93,088	\$	107,478

#### **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 Territory following regulatory approval. Atara retains full rights to Ebvallo in other major markets, including North America, Asia Pacific and Latin America. 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 also agreed to extend the time period for provision of certain services to Pierre Fabre under the Pierre Fabre Commercialization Agreement.

We are responsible at our cost for the conclusion of the ongoing Phase 3 ALLELE clinical study and the Phase 2 multi-cohort clinical study. We will also be responsible at our cost for certain other activities directed to obtaining regulatory approval for Ebvallo for EBV-positive lymphoproliferative disease pursuant to the terms of the Pierre Fabre Commercialization Agreement in Europe. Pierre Fabre will be responsible at its cost for obtaining and maintaining all other regulatory approvals and for commercialization and distribution of Ebvallo in the Territory. We will own any intellectual property rights developed solely by us under the Agreement.

Pierre Fabre paid us an upfront cash payment of \$45.0 million for the exclusive license grant 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. 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, 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.

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 Territory based on a fixed price through December 31, 2023 and cost plus a margin post January 1, 2024. We are responsible for manufacturing and supplying Pierre Fabre with Ebvallo for commercialization in the Territory at Pierre Fabre's cost for a minimum of seven years from the first commercial sale, as defined in the Pierre Fabre Commercialization Agreement, of Ebvallo in the Territory. Following this period, we have the option to transfer the manufacturing responsibility and related manufacturing

technology to a third party contract manufacturing organization ("CMO"), and Pierre Fabre may also elect to directly assume the manufacturing responsibility and receive the related manufacturing technology.

We are also responsible for cell selection services 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. After this period of time, if we agree to continue to provide cell selection services, it shall be at the sole expense of Pierre Fabre.

We have formed a joint steering committee with Pierre Fabre that provides oversight, decision making and implementation guidance regarding the commercialization activities covered under the agreement.

We assessed this arrangement in accordance with ASC 606 and concluded that the promises in the Pierre Fabre Commercialization Agreement represent transactions with a customer. We concluded that the Pierre Fabre Commercialization Agreement includes transfer of intellectual property rights in the form of a license, the potential to manufacture and supply Ebvallo for a minimum of seven years and until tech transfer, the potential to perform cell-selection services for a minimum of three years and until tech transfer, and obligation to participate in the JSC. We concluded that the promises are not distinct because Pierre Fabre cannot benefit from the license without the other services and vice versa. Consequently, the license, manufacture and supply, cell selection and participation in the JSC is a single performance obligation.

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. The \$40.0 million in development milestones met in December 2022 were added to the transaction price upon meeting of the related milestones. Revenue associated with the upfront fee and development milestones for the single performance obligation will be deferred until the initial delivery of services related to the manufacture and supply and cell selection and then recognized over the period during which Pierre Fabre's material right to these services exists. The \$85.0 million in upfront fee and milestones met is recorded as deferred revenue as of December 31, 2022, of which \$8.0 million is included in current liabilities and \$77.0 million is included in long-term liabilities, and we expect to recognize this revenue over the next 12 years.

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, if necessary, adjust our estimate of the transaction price.

#### **Bayer Agreements**

# Research, Development and License Agreement

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

Under the terms of the Bayer License Agreement, we 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 be solely responsible for commercializing the Licensed Products at its cost.

In December 2020, we received an upfront cash payment of \$45.0 million from Bayer for the exclusive license grant, net of applicable withholding taxes, which were fully recovered in August 2021, and an additional \$15.0 million upfront reimbursement payment for certain research and process development activities to be performed by us.

The transaction price at inception consisted of a \$45.0 million upfront payment for the license, \$15.0 million for certain research and process development activities and the \$5.0 million for additional specified translational activities, and this amount was allocated to the single performance obligation. The potential development and commercial milestone payments that we are eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement. None of the future royalty and sales-based milestone payments were included in the transaction price, as the potential payments represent sales-based consideration. We reevaluated the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust our estimate of the transaction price.

## Technology Transfer Agreement

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. Upon entering into the agreement, we invoiced Bayer 20 percent of the total fee of \$15.3 million under the Bayer Tech Transfer Agreement, or \$3.1 million, which we received in the second quarter of 2021 and invoiced 40 percent of the total fee, or \$6.1 million, in the first quarter of 2022.

We assessed this arrangement in accordance with ASC 606 and concluded that the promises in the Bayer Tech Transfer Agreement represent transactions with a customer. We concluded that the Bayer Tech Transfer Agreement should be combined with the Bayer License Agreement and accounted for as a modification of that agreement and that the Bayer Tech Transfer Agreement contains the following promises: (i) technology transfer services and (ii) supply of materials required for the technology transfer services. In accordance with ASC 606, we determined that the technology transfer services and supply of materials required for the technology transfer services were not distinct from each other, as they are highly interdependent upon one another. In addition, we concluded that the technology transfer services and supply of materials required for the technology transfer services were highly interdependent with the license, early-stage R&D and CMC services identified in the Bayer License Agreement. Accordingly, we determined that these promises should be combined into a single performance obligation.

Under the Bayer Tech Transfer Agreement, in order to evaluate the appropriate transaction price, we determined that the \$15.3 million fee constituted the entire consideration to be included in the transaction price, and this amount was allocated to the single performance obligation as identified under the Bayer License Agreement.

We utilize a cost-based input method to recognize revenue based on the amount of actual costs incurred relative to the total budgeted costs expected to be incurred for the combined performance obligation.

#### Manufacturing and Supply Agreement

In March 2021, we 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. Under the Bayer Manufacturing Agreement, we will also provide storage and distribution services to Bayer at a price that is consistent with our standalone selling price for these services.

Upon entering into the Bayer Manufacturing Agreement, Bayer submitted, and we approved, a binding purchase order for manufacturing services and storage services. Any fees for the manufacturing services will be invoiced as follows: (i) 50 percent upon written acceptance by us of the binding purchase order, and (ii) the remainder upon delivery of the certification of analysis of such lots to Bayer. Storage and distribution services are billed monthly as those services are provided to Bayer.

In March 2021, we invoiced Bayer 50 percent of the total estimated supply price of \$13.1 million for manufacturing services under the initial purchase order for the supply of six lots, or \$6.6 million, which we received in the second quarter of 2021. The remainder of the supply price will be billed upon the release of the lots ordered by Bayer.

We assessed this arrangement in accordance with ASC 606 and concluded that the promises in the manufacturing and supply agreement represent transactions with a customer. We concluded that the Bayer Manufacturing Agreement contains the following promises: (i) manufacturing services; (ii) storage services provided on a month-to-month basis; and (iii) distribution services. In accordance with ASC 606, we determined that the manufacturing services for the initial purchase order of six lots, that are expected to be provided prior to completion of the technology transfer, are not distinct as they are highly interdependent on the manufacturing process being developed and transferred under the Bayer License Agreement and the Bayer Tech Transfer Agreement. Accordingly, we determined that these promises should be combined into a single performance obligation. We also determined that each of the other services were distinct and separate performance obligations. We determined that the initial binding order for the manufacture and supply of six lots should be combined with the Bayer License Agreement and accounted for as a modification of that agreement along with the Bayer Tech Transfer Agreement. We also concluded that a binding purchase order from Bayer, together with the Bayer Manufacturing Agreement, form the contract for manufacturing services and storage services and a shipping order from Bayer forms the contract for distribution services. We also determined that the storage services provided on a month-to-month basis and distribution services are distinct and separate performance obligations. All the performance obligations identified above are priced at their standalone selling price.

Under the Bayer Manufacturing Agreement, in order to evaluate the appropriate transaction price, we determined that the \$13.1 million fee constituted the entire consideration to be included in the transaction price, and this amount was allocated to the single

performance obligation as identified under the Bayer License Agreement. Revenue for the manufacturing services for the initial six lots will be recognized based on the amount of actual costs incurred relative to the total budgeted costs expected to be incurred for the combined performance obligation. Revenue for the storage services will be recognized over time as those services are provided. Revenue for the distribution services will be recognized at a point in time when the product is delivered to a clinical site designated by Bayer.

#### Bayer Agreements Termination and Revenue Recognition

In May 2022, Bayer notified us of its decision to terminate the Bayer Agreements, and on August 2, 2022, we entered into the Bayer Termination Agreement with an effective date of July 31, 2022. Upon the termination effective date, full product development 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 the year ended December 31, 2022, under the Bayer Agreements and Bayer Termination Agreement. For the year ended December 31, 2021, we recognized license and collaboration revenue of \$19.8 million under the Bayer Agreements. There was no deferred revenue related to the Bayer Agreements as of December 31, 2022, compared to \$51.5 million as of December 31, 2021. No development or sales-based milestone payments have been earned or received.

#### 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"), net of certain transaction expenses, to Atara, 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. We received the Investment Amount, net of certain transaction costs, from HCRx on December 30, 2022.

Under the HCRx Agreement, HCRx is entitled to receive tiered royalties on net sales of Ebvallo in the Territory (as defined in the Pierre Fabre Commercialization Agreement) 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 will 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. Over the life of the arrangement, the actual effective interest rate will be affected by the amount and timing of the royalty and milestone payments received by HCRx and changes in our forecasted payments to HCRx. At each reporting date, we will reassess our estimate of total future royalty payments to be received by 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, 2022:

For the year ended

	De	cember 31,
		2022
	(in	thousands)
Liability related to the sale of future revenues, beginning balance	\$	_
Proceeds from sale of future revenues, net		30,605
Less: debt issuance costs		(368)
Liability related to the sale of future revenues, ending balance	\$	30,237

#### 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 are assisting them in the transition of certain functions, including, but not limited to, information technology, finance and technical operations. FDB will reimburse 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 year ended December 31, 2022. Any amounts owed to us by FDB under the TSA as of December 31, 2022 are included in other current assets.

#### 8.Leases

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. Subsequently, we have moved our corporate headquarters to our office space 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 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 lease 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 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 Atara's 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.

The maturities of lease liabilities under our operating and finance leases as of December 31, 2022 were as follows:

	Operating Leases		Fin	ance Leases
Years Ending December 31,		(in thousands)		
2023	\$	19,158	\$	1,339
2024		18,035		1,242
2025		17,880		1,263
2026		16,557		1,285
2027		5,631		436
Thereafter		15,778		_
Total lease payments	\$	93,039	\$	5,565
Less: amount representing interest		(22,169)		(1,088)
Present value of lease liabilities	\$	70,870	\$	4,477
Balance as of December 31, 2022				
Other current liabilities	\$	12,806	\$	834
Operating lease liabilities - long-term		58,064		_
Other long-term liabilities		_		3,643
Total	\$	70,870	\$	4,477

The components of lease cost were as follows:

	Year Ended December 31, 2022		Year Ended December 31, 2021 (in thousands)		Year Ender 1 December 31, 2	
Operating lease cost:						
Operating lease cost	\$	14,245	\$	3,827	\$	3,020
Short-term lease cost		386		836		987
Total operating lease cost	\$	14,631	\$	4,663	\$	4,007
Finance lease cost:						
Amortization expense	\$	872	\$	244	\$	389
Interest on lease liabilities		373		29		60
Total finance lease cost	\$	1,245	\$	273	\$	449

Other information related to leases was as follows:

	 Year Ended December 31, 2022 (in thousands,		Year Ended ember 31, 2021 lease term and d			
Supplemental Cash Flows Information						
Cash paid for amounts included in the measurement of lease liabilities:						
Operating cash flows for operating leases	\$ 13,417	\$	3,738	\$	2,878	
Operating cash flows for finance leases	335		32		62	
Financing cash flows for finance leases	518		254		389	
-						
Operating lease assets obtained in exchange for lease obligations:	\$ 50,779	\$	13,427	\$	_	
Finance lease assets obtained in exchange for lease obligations:	4,795		_		281	
Non-cash increase to operating lease assets due to remeasurement of lease liabilities:	_		1,760		639	
Weighted Average Remaining Lease Term						
Operating leases	5.9 years		9.2 years		9.4 years	
Finance leases	4.2 years		1.0 years		1.7 years	
Weighted Average Discount Rate						
Operating leases	9.9 %	6	9.6 %	6	10.3	
Finance leases	10.4 %		9.7 %	6	9.7 9	

## **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, 2022 and December 31, 2021, 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 is expected to include 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 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 will be paid between October 2022 and November 2023. All of the costs are cash expenditures and primarily represent one-time termination benefits.

We recorded the following restructuring charges associated with the reduction in force:

	d December 31, 2022 ousands)
Research and development expense	\$ 2,544
General and administrative expense	3,420
Total restructuring charges	\$ 5,964

The following restructuring liability activity was recorded in connection with the reduction in force for the year ended December 31, 2022, with all of the \$1.5 million liability balance as of December 31, 2022 included within other current liabilities on the accompanying consolidated balance sheet:

	Total Restru	icturing Charges
	(in th	ousands)
Liability balance, January 1, 2022	\$	_
Charges		5,964
Cash payments		(4,419)
Liability balance, December 31, 2022	\$	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, Atara will retain non-exclusive rights to the licensed products.

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

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 19 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology that we exercised in June 2018. We further amended and restated our license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019 to terminate our license to certain rights. 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 next-generation CAR T programs from Moffitt Cancer Center in August 2018, and we agreed to collaborate through sponsored research in connection with each of these licenses. We also licensed rights related to our MSK-partnered next-generation CAR T programs from the National Institutes of Health in December 2018.

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when the underlying milestones are achieved or royalties are earned. As of December 31, 2022 and 2021, 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. In February 2023, we amended the CRL MSA to extend the term until the earlier of September 30, 2023 or receipt of certain batches of our product and product candidates.

#### **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 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, 2022 and December 31, 2021, there were no material amounts accrued related to contract termination charges. Based on our expectations of patients and demand for product in the EU, we believe our current inventory of Ebvallo is sufficient to supply commercial demand in the EU until the end of 2023.

## 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, 2022 are set forth below:

Calendar		Commitment as of December 31, 2022
	(in	thousands)
2023	\$	19,420
2024		14,085
2025		13,308
2026		9,605
2027		3,388
		59,806
Total	\$	

We have incurred \$14.2 million against such minimum commitments for the year ended December 31, 2022. No such amounts were recorded for the years ended December 31, 2021 and 2020.

As of December 31, 2022, we have accrued approximately \$9.2 million in research and development expenses related to minimum purchase commitments. As of December 31, 2021, no such amounts were accrued.

#### **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, 2022 and 2021.

#### 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, 2022 and 2021.

# **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 ("Maximum Ownership Percentage"). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the Maximum Ownership Percentage to any other percentage not to exceed 19.99%. As of December 31, 2022, pre-funded warrants to purchase 2,888,526 shares of our common stock from the July 2019 offering were outstanding.

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

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

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. As of December 31, 2022, all of the pre-funded warrants issued and sold as part of the 2020 underwritten public offerings were outstanding.

#### **ATM Facilities**

In the past three years, we have entered into two separate sales agreements with Cowen and Company, LLC (Cowen): in February 2020 (the "2020 ATM Facility") and in November 2021 (the "2021 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 and the 2021 ATM Facility did not replace the 2020 ATM Facility in any way. 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 fiscal year ended December 31, 2021, we sold an aggregate of 6,240,601 shares of common stock under the ATM facilities, at an average price of \$16.23 per share, for gross proceeds of \$101.3 million and net proceeds of \$98.9 million, after deducting commissions and other offering expenses payable by us.

During the year ended December 31, 2022, we sold an aggregate of 1,618,672 shares of common stock under the 2021 ATM Facility, 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.

As of December 31, 2022, we had fully utilized the 2020 ATM Facility and we had \$55.9 million of common stock remaining and available to be sold under the 2021 ATM Facility.

#### **Equity Incentive Plans**

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

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

Under the terms of the 2014 EIP, we may grant stock options, RSAs and RSUs to employees, directors, consultants and other service providers. RSUs generally vest over four years. The fair value of RSUs, including those with performance conditions, is determined as the closing stock price on the date of grant.

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.

In 2020, we granted performance-based awards to certain of our employees that provide for the issuance of common stock if specified Company performance criteria related to our clinical programs are achieved. The number of performance-based awards that ultimately vests depends upon if, when and which performance criteria are achieved, as well as the employee's continuous service, as defined in the 2014 EIP, through the date of vesting. None of the performance criteria were achieved by the required deadlines set forth in the award agreements and they were subsequently forfeited.

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 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 have been achieved as of December 31, 2022 and the amount of outstanding awards is not material.

As of December 31, 2022, a total of 18,781,047 shares of common stock were reserved for issuance under the 2014 EIP, of which 4,702,072 shares were available for future grant and 14,078,975 shares were subject to outstanding options and RSUs, including performance-based awards. As of December 31, 2022, 5,191,916 shares of common stock were reserved for issuance under the Inducement Plan, of which 1,916,728 shares were available for future grant and 3,275,188 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:

	RSU Shares	Js	Weighted Average Grant Date Fair Value
Balance as of December 31, 2021	5,592,358	\$	16.22
Granted	5,947,417	\$	8.26
Forfeited	(2,583,871)	\$	13.27
Vested	(2,247,296)	\$	15.29
Balance as of December 31, 2022	6,708,608	\$	10.61

The weighted average grant date fair value of RSUs granted during the years ended December 31, 2022, 2021 and 2020 was \$8.26, \$16.42 and \$12.19, respectively. The estimated fair value of RSUs that vested in the years ended December 31, 2022, 2021 and 2020 was \$34.4 million, \$27.1 million and \$23.6 million, respectively. As of December 31, 2022, there was \$63.5 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.5 years. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2022 was \$22.0 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 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. During 2021, we settled 1,553,893 shares underlying RSUs, of which 154,341 shares underlying RSUs were net settled by withholding 61,385 shares. The value of the shares underlying RSUs withheld was \$1.2 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.

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

			Weighted Average		
	Shares	eighted Average Exercise Price	Remaining Contractual Term (Years)	Inti	aggregate insic Value thousands)
Balance as of December 31, 2021	9,219,837	\$ 20.81	6.4	\$	12,810
Granted	3,615,971	9.06			
Exercised	(15,989)	8.96			
Forfeited or expired	(2,174,264)	20.62			
Balance as of December 31, 2022	10,645,555	\$ 16.88	6.4	\$	42
Vested and expected to vest as of December 31, 2022	10,645,555	\$ 16.88	6.4	\$	42
Exercisable as of December 31, 2022	6,061,634	\$ 21.21	4.7	\$	_

\*\*\* \* \* \* \* \* \* \*

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2022 and the exercise price of outstanding, in-the-money options. As of December 31, 2022, there was \$29.2 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.4 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.

Options for 15,989, 246,867, and 268,938 shares of our common stock were exercised during the years ended December 31, 2022, 2021 and 2020, with an intrinsic value of \$0.1 million, \$0.8 million and \$1.0 million, respectively. As we believe it is more likely than not that no stock option related tax benefits will be realized, we do not record any net tax benefits related to exercised options.

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

	Year ended December 31,					
	2022		2021		2020	
Assumptions:						
Expected term (years)	6.0		6.0		6.0	
Expected volatility	73.2 %	6	75.9 %	6	76.8 %	
Risk-free interest rate	2.1 %	6	0.9 %	6	0.8 %	
Expected dividend yield	0.0 %	6	0.0 %	6	0.0 %	
Fair Value:						
Weighted-average estimated grant date fair value per share	\$ 5.88	\$	10.52	\$	7.96	
Options granted	3,615,971		2,643,378		2,641,125	
Total estimated grant date fair value	\$ 21,261,909	\$	27,808,000	\$	21,023,000	

The estimated fair value of stock options that vested in the years ended December 31, 2022, 2021 and 2020 was \$23.2 million, \$26.6 million and \$29.4 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. The Company recorded \$1.1 million, \$1.7 million and \$1.8 million of expense related to the 2014 ESPP in the years ended December 31, 2022, 2021 and 2020, respectively. A total of 417,081, 319,190 and 282,514 shares were purchased under the ESPP during the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, there was \$0.4 million of unrecognized stock-based compensation expense related to the ESPP that is expected to be recognized by the end of second quarter of 2023.

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, 2022, there were 2,048,280 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, 2022:

	Total Shares Reserved
2014 Equity Incentive Plan	18,781,047
2018 Inducement Plan	5,191,916
2014 Employee Stock Purchase Plan	676,070
Total reserved shares of common stock	24,649,033

# **Stock-based Compensation Expense**

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

	Year Ended December 31,						
	2022		2021		2020		
		(in	thousands)				
Research and development	\$ 31,363	\$	32,063	\$	31,527		
General and administrative	22,475		21,802		19,824		
Total stock-based compensation expense	\$ 53,838	\$	53,865	\$	51,351		

## 12.Income Taxes

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

	Year Ended December 31,					
	2022		2021		2020	
	(in thousands)					
United States	\$ (228,395)	\$	(340,301)	\$	(306,758)	
Foreign	105		206		153	
Total loss before provision for income taxes	\$ (228,290)	\$	(340,095)	\$	(306,605)	

The components of provision for income taxes were as follows in each period presented:

	Year Ended December 31, 2022 2021 (in thousands)				2020
Current provision for income taxes:					
State	\$ _	\$	4	\$	2
Foreign	12		42		13
Total current provision for income taxes	\$ 12	\$	46	\$	15

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

	Year Ended December 31,				
	2022	2021	2020		
Federal income taxes at statutory rate	21.0 %	21.0 %	21.0 %		
Research tax credits	7.8 %	_	_		
Stock-based compensation	(3.8 %)	(2.0 %)	(2.4 %)		
Other	(0.2 %)	(0.3 %)	0.2 %		
Change in valuation allowance	(24.8 %)	(18.7 %)	(18.8 %)		
Effective tax rate	0.0 %	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,			
	:	2022	2	2021	
		(in thous	ands)		
Deferred tax assets:					
Net operating loss carryforwards	\$	302,591	\$	308,997	
Capitalized research expenses		50,522		10,499	
Tax credit carryforwards		19,427		1,580	
Stock-based compensation		19,201		24,181	
Deferred revenue		10,069		12,133	
Operating lease liabilities		15,857		7,972	
License fees		6,877		8,716	
Other		13,169		9,414	
Total deferred tax assets		437,713		383,492	
Valuation allowance		(422,493)		(376,071)	
Total deferred tax assets		15,220		7,421	
Deferred tax liabilities:					
Operating lease assets		(15,220)		(7,421)	
Total deferred tax liabilities		(15,220)		(7,421	
	ф		Ф.		
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 \$43.7 million, partially offset by amortization on research expenses capitalized in prior years.

Our tax credit carryforwards increased by \$17.8 million, as compared to 2021, 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, 2022 and 2021. 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 \$46.4 million for the year ended December 31, 2022 due to the increase in our net deferred tax assets.

In August 2022, the CHIPS and Science Act ("CHIPS Act") and Inflation Reduction Act ("IRA") were enacted, neither of which are expected to have a material impact to our financial statements. In addition, effective January 1, 2022, the California net operating loss deduction and temporary limit on business credits have been reinstated.

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 net operating losses generated in tax years beginning on or after January 1, 2018 may be carried forward indefinitely, but the utilization of such federal net operating losses 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, 2022, for federal income tax purposes, we had net operating loss carryforwards of approximately \$1.0 billion of which \$22.6 million begin to expire in 2036 and the remaining may be carried forward indefinitely, research & development tax credits of \$24.0 million which begin to expire in 2032, and orphan drug tax credits of \$106.9 million which begin to expire in 2035. During 2022, we utilized \$42.7 million federal net operating losses to offset taxable income. For state income tax purposes, we had net operating loss carryforwards of approximately \$1.3 billion which begin to expire in 2030, research & development tax credits of \$38.0 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 net operating loss 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 net operating loss 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, 2022. The study concluded that we have experienced ownership changes since inception and that our utilization of net operating loss carryforwards will be subject to annual limitations. However, it is not expected that the annual limitations will result in the expiration of tax attribute carryforwards prior to utilization.

The changes in the balance of gross unrecognized tax benefits, which excludes interest and penalties, for the years ended December 31, 2020, 2021 and 2022 are as follows:

	(In thousands)
Balance as of January 1, 2020	\$ 86,000
Gross increases for tax positions related to current year	24,648
Gross increases for tax positions related to prior year	_
Gross decreases for tax positions related to prior year	(47)
Balance as of December 31, 2020	110,601
Gross increases for tax positions related to current year	28,171
Gross increases for tax positions related to prior year	5,295
Gross decreases for tax positions related to prior year	_
Balance as of December 31, 2021	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

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, 2022 and 2021 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, 2022, we are not permanently reinvested with respect to its foreign earnings and has 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:

	December 31, 2022		er 31, 1
	(in thou	sands)	
Raw Materials	\$ 1,214	\$	_
Work-in-process	372		_
Total inventories	\$ 1,586	\$	

# Property and equipment, net

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

	De	cember 31, 2022	De	ecember 31, 2021
	(in thousands)			)
Leasehold improvements	\$	875	\$	50,142
Lab equipment		14,797		14,060
Machinery and equipment		572		5,228
Computer equipment and software		1,149		4,245
Furniture and fixtures		1,297		2,518
Construction in progress		32		6,325
Property and equipment, gross		18,722		82,518
Less: accumulated depreciation and amortization		(12,422)		(28,738)
Property and equipment, net	\$	6,300	\$	53,780

Depreciation and amortization expense was \$5.7 million, \$9.3 million and \$8.3 million for the years ended December 31, 2022, 2021 and 2020, respectively.

# Other current liabilities

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

	ember 31, 2022		mber 31, 2021
	(in thous	sands)	
Accrued operating expenses	\$ 7,435	\$	5,960
Current portion of operating lease liabilities	12,806		2,582
Current portion of finance lease liabilities	834		171
Other accrued liabilities	319		344
Total other current liabilities	\$ 21,394	\$	9,057

## 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, 2022. 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, 2022 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 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, 2022 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, 2022. The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in its report which is included in this Item 9A of this Annual Report on Form 10-K.

#### Inherent Limitations on Controls and Procedures

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

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2022, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

# Changes in Internal Control over Financial Reporting

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

# Report of Independent Registered Public Accounting Firm

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

#### Report of Independent Registered Public Accounting Firm

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

#### **Opinion on Internal Control over Financial Reporting**

We have audited the internal control over financial reporting of Atara Biotherapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2022, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheet and related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows as of and for the year ended December 31, 2022, of the Company and our report dated February 8, 2023, expressed an unqualified opinion on those financial statements.

## **Basis for Opinion**

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

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

#### Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ DELOITTE & TOUCHE LLP

San Francisco, California February 8, 2023

# Item 9B. Other Information

None.

# 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 2023 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, 2022, 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	Inc Form	Incorporated by Reference rm Exhibit Filing I		Filed ate Herewith	
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 under the 2014 Equity Incentive Plan	10-Q	10.1	11/07/2019		
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 Employment Agreement by and between Atara Biotherapeutics, Inc. and its executive officers.	10-Q	10.4	08/01/2018		
10.11*	Form of Executive Employment Agreement	10-Q	10.2	08/08/2019		
10.12*	Executive Employment Agreement, dated May 23, 2019, by and between Pascal Touchon and Atara Biotherapeutics, Inc.	8-K	10.1	05/28/2019		
10.13†	Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015	S-1	10.30	06/29/2015		
10.14†	Amendment No. 1 to the Exclusive License Agreement, by and between Atara  Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of August 30,  2018	10-K	10.14	02/26/2019		
10.15†	Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Council of the Queensland Institute of Medical Research, dated September 23, 2016, as amended	10-Q	10.1	08/01/2018		
10.16†	Amended and Restated Research and Development Collaboration Agreement, by and between Atara Biotherapeutics, Inc. and the Council of the Queensland Institute of Medical Research, dated September 23, 2016, as amended	10-Q	10.2	08/01/2018		
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Exhibit Number	Exhibit Description	Form	Incorporated by Referen	nce Filing Date	Filed Herewith
10.17+	Second Amended and Restated Research and Development Collaboration Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 28, 2019	10-Q	10.3	11/07/2019	
10.18+	Second Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 28, 2019	10-Q	10.4	11/07/2019	
10.19+	Third Amended and Restated Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 26, 2020	10-Q	10.1	11/09/2020	
10.20+	Third Amended and Restated Research and Development Collaboration Agreement, by and between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated August 26, 2020	10-Q	10.2	11/09/2020	
10.21†	Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated August 10, 2015, as amended	10-Q	10.3	08/01/2018	
10.22+	Amended and Restated Amendment No. 2 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 4, 2018	10-Q	10.5	11/07/2019	
10.23+	Amendment No. 3 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated June 28, 2019	10-Q	10.6	11/07/2019	
10.24+	Amendment No. 4 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 4, 2019	10-K	10.22	02/27/2020	
10.25+	Amendment No. 5 to the Development and Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated November 27, 2019	10-K	10.23	02/27/2020	
10.26+	Commercial Manufacturing Services Agreement, by and between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated January 1, 2020	10-K	10.24	02/27/2020	
10.27+	Amendment No. 1 to Commercial Manufacturing Services Agreement, between Atara Biotherapeutics, Inc. and Cognate BioServices, Inc., dated September 1, 2021	10-Q	10.1	11/04/2021	
10.28	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	
10.29	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	
10.30	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	
10.31+	Research, Development and License Agreement, by and between Atara Biotherapeutics, Inc. and Bayer AG, dated December 4, 2020	10-Q	10.1	05/04/2021	
10.32	Lease Agreement between LA Region No. 2, LLC and Atara Biotherapeutics, Inc. dated March 17, 2021	10-Q	10.2	05/04/2021	
10.33+	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	
10.34+	Deed of Amendment Number 1 to Third Amended and Restated License Agreement dated April 21, 2021	10-Q	10.1	08/09/2021	
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Exhibit Number	Exhibit Description	Form	Incorporated by Reference	rence Filing Date	Filed Herewith
10.35+	Commercialization Agreement by and between Atara Biotherapeutics, Inc. and Pierre Fabre Medicament, dated October 2, 2021	10-K	10.35	02/28/2022	
10.36	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	
10.37+	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	
10.38+	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	
10.39*	Form of Atara Biotherapeutics, Inc. Executive Employment Agreement	10-K	10.39	02/28/2022	
10.40+	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	
10.41	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	
10.42	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	
10.43+	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	
10.44	Termination, Amendment and Program Transfer Agreement dated August 2, 2022, by and between Atara Biotherapeutics, Inc., and Bayer AG+	10-Q	10.2	11/08/2022	
10.45+	Amendment No. 1 to the Commercialization Agreement dated September 28, 2022, by and between Atara Biotherapeutics, Inc. and Pierre Fabre Medicament	10-Q	10.3	11/08/2022	
10.46+	Purchase and Sale Agreement between Atara Biotherapeutics, Inc., and HCR Molag Fund, L.P., dated December 20, 2023				X
21.1	<u>List of Subsidiaries</u>				X
23.1	Consent of Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (included on signature page)				
31.1	Certification of the Chief Executive Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X

Exhibit			Incorporated by Refer	rence	Filed
Number 31.2	Exhibit Description  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	Form	Exhibit	Filing Date	Herewith X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

<sup>†</sup> Confidential treatment has been granted for a portion of this exhibit.

(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.

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

<sup>\*</sup> Indicates management contract or compensatory plan or arrangement.

#### **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 8<sup>th</sup> day of February, 2023.

#### Atara Biotherapeutics, Inc.

By: /s/ Pascal Touchon Pascal Touchon

President and Chief Executive Officer

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

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

Signature	Title	Date	
/s/ Pascal Touchon			
Pascal Touchon	President, Chief Executive Officer and Director (principal executive officer)	February 8, 2023	
/s/ Utpal Koppikar			
Utpal Koppikar	Chief Financial Officer (principal financial and accounting officer)	February 8, 2023	
/s/ Carol G. Gallagher			
Carol G. Gallagher, Pharm. D.	Director, Chair	February 8, 2023	
/s/ Eric L. Dobmeier			
Eric L. Dobmeier	Director	February 8, 2023	
/s/ Matthew K. Fust			
Matthew K. Fust	Director	February 8, 2023	
/s/ William K. Heiden			
William K. Heiden	Director	February 8, 2023	
/s/ Ameet Mallik			
Ameet Mallik	Director	February 8, 2023	
/s/ Maria Grazia Roncarolo			
Maria Grazia Roncarolo, M.D.	Director	February 8, 2023	
/s/ Beth Seidenberg			
Beth Seidenberg, M.D.	Director	February 8, 2023	
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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** 

PURCHASE AND SALE AGREEMENT

dated as of December 20, 2022

between

ATARA BIOTHERAPEUTICS, INC.

and

HCR MOLAG FUND, L.P.

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# **Exhibits**

Exhibit A: Licensee Instruction Exhibit B: Form of Bill of Sale Exhibit C: Disclosure Schedule

Exhibit D: Commercialization Agreement

Exhibit E: MSK Agreement

## PURCHASE AND SALE AGREEMENT

This PURCHASE AND SALE AGREEMENT (this "Purchase and Sale Agreement"), dated as of December 20, 2022 (the "Effective Date"), is entered into by and between Atara Biotherapeutics, Inc., a Delaware corporation (the "Seller"), and HCR Molag Fund, L.P., a Delaware limited partnership (the "Purchaser").

## **RECITALS**:

WHEREAS, the Seller has the right to receive royalties and certain milestone payments under the Commercialization Agreement; and

WHEREAS, the Seller desires to sell, assign, transfer, convey and grant to the Purchaser, and the Purchaser desires to purchase, acquire and accept from the Seller, the Purchased Royalties described herein, upon and subject to the terms and conditions set forth in this Purchase and Sale Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual agreements, representations and warranties set forth herein and of other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties covenant and agree as follows:

# ARTICLE I DEFINED TERMS AND RULES OF CONSTRUCTION

Section 1.1 Defined Terms. The following terms, as used herein, shall have the following respective meanings:

"Additional Indication" has the corresponding meaning as set forth in the Commercialization Agreement.

"Affiliate" means, with respect to any designated Person, any other Person that, directly or indirectly, controls, is controlled by or is under common control with such designated Person. For purposes of this definition, "control" of a Person means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise, and the terms "controlled" and "controlling" have meanings correlative to the foregoing. Notwithstanding anything herein to the contrary, in no event shall Purchaser or any of its Affiliates be considered an "Affiliate" of Seller.

"Amendment" has the meaning set forth in the definition of Commercialization Agreement.

"Applicable Law" means, with respect to any Person, all laws, rules, regulations and orders of Governmental Authorities applicable to such Person or any of its properties or assets.

"Atara 205 Study" has the corresponding meaning as set forth in the Commercialization Agreement.

"Atara 302 Study" has the corresponding meaning as set forth in the Commercialization Agreement.

"Bankruptcy Code" means Title 11 of the United States Code entitled "Bankruptcy," as now and hereafter in effect, or any successor statute.

"Bankruptcy Event" means the occurrence of any of the following in respect of any Person: (a) an admission in writing by such Person of its inability to pay its debts as they become due or a general assignment by such Person for the benefit of creditors; (b) the filing of any petition or answer by such Person seeking to adjudicate itself as bankrupt or insolvent, or seeking for itself any liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of such Person or its debts under any law relating to bankruptcy, insolvency, receivership, winding-up, liquidation, reorganization, examination, relief of debtors or other similar law now or hereafter in effect, or seeking, consenting to or acquiescing in the entry of an order for relief in any case under any such law, or the appointment of or taking possession by a receiver, trustee, custodian, liquidator, examiner, assignee, sequestrator or other similar official for such Person or for any substantial part of its property; (c) corporate or other entity action taken by such Person to authorize any of the actions set forth in clause (a) or (b) of this definition; or (d) without the consent or acquiescence of such Person, the entering of an order for relief or approving a petition for relief or reorganization or any other petition seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or other similar relief under any present or future bankruptcy, insolvency or similar statute, law or regulation, or the filing of any such petition against such Person, or, without the consent or acquiescence of such Person, the entering of an order appointing a trustee, custodian, receiver or liquidator of such Person or of all or any substantial part of the property of such Person, in each case where such petition or order shall remain unstayed or shall not have been stayed or dismissed within 60 days from entry thereof. Bankruptcy Event shall include any Insolvency Event (as such term is defined in the Commercialization Agreement). Unless otherwise specified, references to Bankruptcy Event in this Purchase and Sale Agreement shall refer to a Bankruptcy Event with respect to the Seller or its Subsidiary, Atara Biotherapeutics Ireland Limited.

"Bill of Sale" means that certain bill of sale, dated as of the Closing Date, executed by the Seller and the Purchaser, substantially in the form of Exhibit B.

"Business Day" means any day that is not a Saturday, Sunday or other day on which commercial banks in New York City are authorized or required by Applicable Law to remain closed.

"Calendar Quarter" has the corresponding meaning as set forth in the Commercialization Agreement.

"Calendar Year" has the corresponding meaning as set forth in the Commercialization Agreement.

"Closing" has the meaning set forth in Section 6.1.

"Closing Date" has the meaning set forth in Section 6.1.

"Code" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations thereunder.

"Commercialization" has the corresponding meaning as set forth in the Commercialization Agreement.

"Commercialization Agreement" means that certain Commercialization Agreement by and between Seller and Licensee, dated October 2, 2021, as amended by Amendment No. 1 to the Commercialization Agreement dated September 27, 2022 (the "Amendment").

- "Competitor" means any Person [[\*\*\*]] engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the business of [[\*\*\*]], but shall not include [[\*\*\*]] any Competitor and does not, nor do any of its Affiliates, have [[\*\*\*]].
- "Credit Event" means any Bankruptcy Event or similar proceeding of Licensee, or financial distress of Licensee, as a result of which the Licensee fails to pay, or is delayed in paying, all or a portion of the Purchased Royalties.
  - "Defaulting Party" has the meaning set forth in Section 5.5(d).
  - "Development" has the corresponding meaning as set forth in the Commercialization Agreement.
  - "Disclosure Schedule" means the Disclosure Schedule dated as of the date hereof and attached hereto as Exhibit C.
  - "Disputes" has the meaning set forth in Section 3.9(c).
  - "Dollar" or the sign "\$" means United States dollars.
  - "EBV+PTLD" has the corresponding meaning as set forth in the Commercialization Agreement.
  - "EMA" has the corresponding meaning as set forth in the Commercialization Agreement.
  - "ERISA" means the Employee Retirement Income Security Act of 1974, as amended from time to time.
  - "Escrow Account" means the escrow account created pursuant to the Escrow Agreement.
- "Escrow Agreement" means an Escrow Agreement to be entered into by and among the Seller, the Purchaser and an escrow agent, in form and content acceptable to the Seller and the Purchaser.
  - "European Commission" means the European Union's ("EU") independent executive arm.
  - "Excluded Liabilities and Obligations" has the meaning set forth in Section 2.3.
- "Existing Confidentiality Agreement" means that certain Confidentiality Agreement by and between Seller and Purchaser, dated December 5, 2019, as amended on November 10, 2020 and June 23, 2022.
  - "FDA" means the U.S. Food and Drug Administration and any successor agency thereto.
  - "Field" has the corresponding meaning as set forth in the Commercialization Agreement.
  - "Fundamental Representations" has the meaning set forth in Section 7.5(a).
  - "GAAP" means generally accepted accounting principles in effect in the United States from time to time.
- "GMP" means all applicable then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as set forth

in FDA regulations in 21 C.F.R. Parts 210 and 211 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to current good Manufacturing practices prescribed by the European Community under provisions of "The Rules Governing Medicinal Products in the European Community, Volume 4, Good Manufacturing Practices, Annex 13, Manufacture of Investigational Medicinal Products, December 2010," (or such other foreign equivalent regulatory standards in any other country or jurisdiction).

"Governmental Authority" means the government of the United States, any other national supranational, regional, federal, state, provincial, municipal, local or other governmental, or any political subdivision thereof, and any agency, authority (including supranational authority), commission, instrumentality, regulatory body, court, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government, including each Patent Office, the FDA, the EMA, the European Commission and the competent authorities of the EU Member States, and any other government authority in any country.

"Intellectual Property Rights" means Atara Intellectual Property (as defined in the Commercialization Agreement).

"Know-How" has the corresponding meaning as set forth in the Commercialization Agreement.

"Knowledge" means, with respect to the Seller, (a) for purposes of <u>ARTICLE III</u>, the actual knowledge of any of the employees of the Seller identified on <u>Schedule 1.1</u>, after having conducted reasonable internal inquires, and (b) for all other purposes of this Purchase and Sale Agreement, the actual knowledge, as of a specified time, of any of the employees of the Seller identified on <u>Schedule 1.1</u> or any successor to any such employee holding the same or substantially similar employee position at such time, after having conducted reasonable internal inquires.

"<u>Licensed Patents</u>" means Atara Patent Rights (as defined in the Commercialization Agreement) and any other Patent Rights (as defined in the Commercialization Agreement) within the Intellectual Property Rights.

"Licensee" means Pierre Fabre Medicament.

"Licensee Instruction" means the direction letter to Licensee, in the form attached as Exhibit A, dated as of the Closing Date.

"Lien" means any security interest, mortgage, pledge, hypothecation, assignment, deposit arrangement, encumbrance, lien (statutory or otherwise), charge against or interest in property or other priority or preferential arrangement of any kind or nature whatsoever, including any conditional sale or any sale with recourse, or any other restriction on transfer.

"Loss" means any loss, liability, cost, expense (including reasonable costs of investigation and defense and reasonable attorneys' fees and expenses), charge, fine, penalty, obligation, judgment, award, assessment, claim or cause of action.

"Manufacturing and Supply Agreement" or "MSA" has the corresponding meaning as set forth in the Commercialization Agreement.

"Marketing Authorization" or "MA" has the corresponding meaning as set forth in the Commercialization Agreement.

"Material Adverse Effect" means a material adverse effect on (a) the legality, validity or enforceability of this Purchase and Sale Agreement, the MSK Agreement, the Manufacturing and Supply Agreement, or the Commercialization Agreement, (b) the ability of the Seller to perform its obligations under this Purchase and Sale Agreement, the MSK Agreement, the Manufacturing and Supply Agreement, or the Commercialization Agreement, (c) the rights of the Seller under the Commercialization Agreement related to the Purchased Royalties, (d) the rights or remedies of the Purchaser under this Purchase and Sale Agreement, or (e) the timing, amount or duration of the Purchased Royalties (but excluding in each case any event, circumstance or change based on market conditions generally applicable to the industry in which the Seller operates or in any specific jurisdiction or geographical area, such as drug reimbursement rates or the commercial launch of a potentially competitive product).

"Milestone Payments" means all of the Seller's right, title and interest in and to:

(a) [[\*\*\*]]
(b) [[\*\*\*]]

"MSK" means the Memorial Sloan Kettering Cancer Center.

"MSK Agreement" means that certain First Amended and Restated Exclusive License Agreement by and between MSK and Seller, dated March 22, 2021.

"[[\*\*\*]]" has the meaning set forth in clause (a)(i) of the definition of "Milestone Payments."

"[[\*\*\*]]" has the meaning set forth in clause (a)(i) of the definition of "Milestone Payments."

"Multi-Cohort Indication" has the corresponding meaning as set forth in the Commercialization Agreement.

"Mutually Agreed" means:

(a) [[\*\*\*]];

(b) [[\*\*\*]]; or

(c) [[\*\*\*]].

"Net Sales" has the corresponding meaning as set forth in the Commercialization Agreement.

"New Arrangement" has the meaning set forth in Section 5.6(a).

"Party" shall mean the Seller or the Purchaser, as the context requires, and "Parties" shall mean, collectively, the Seller and the Purchaser.

"<u>Patent Office</u>" means the applicable patent office, including the United States Patent and Trademark Office and any comparable foreign patent office, for any patent rights.

"Permitted Liens" means any (i) Liens for Taxes not yet due and payable or which are being contested in good faith and for which adequate reserves have been established in accordance with GAAP, (ii) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, materialmen and suppliers and other Liens imposed by law (other than any such Lien imposed pursuant to Section 401(a)(29) or 412(n) of the Code or by ERISA) or pursuant to customary reservations or retentions of title arising in the ordinary course of business for amounts not yet due, (iii) any Liens created, permitted or required by the Transaction Documents in favor of the Purchaser or its Affiliates, (iv) pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation, (v) deposits to secure the performance of bids, trade contracts and leases (other than indebtedness), statutory obligations, surety and appeal bonds, indemnity and performance bonds and other obligations of a like nature incurred in the ordinary course of business so long as no foreclosure, sale or similar proceedings have been commenced with respect to any portion of the Purchased Royalties on account thereof; (vi) normal and customary banker's liens and rights of setoff upon deposits of cash in favor of banks or other depository institutions, in each case granted in the ordinary course of business in favor of the bank or banks with which such accounts are maintained, as part of a bank's standard terms and conditions, (vii) any Liens in favor of, or granted to, Licensee pursuant to the Commercialization Agreement, (viii) licenses or sublicenses granted to others in the ordinary course of business or otherwise and not interfering in any respect with the Purchased Royalties, the Intellectual Property Rights, or the security interests granted pursuant to <u>Section 2.1</u>, (ix) Liens of a collection bank arising under Section 4-210 of the UCC on items in the course of collection, and (x

"<u>Permitted Reduction</u>" means any adjustments, modifications, credits, offsets, reductions, or deductions to the Royalties or Milestone Payments permitted under the Commercialization Agreement.

"Permitted Tax Withholding" means any Tax withholding expressly permitted under Section 11.11(b) of the Commercialization Agreement.

"Person" means any natural person, firm, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Authority or any other legal entity, including public bodies, whether acting in an individual, fiduciary or other capacity.

"Product" has the corresponding meaning as set forth in the Commercialization Agreement.

"Purchase and Sale Agreement" has the meaning set forth in the preamble.

"Purchase Price" has the meaning set forth in Section 2.2.

"<u>Purchased Royalties</u>" means, for the period commencing on the Closing Date and thereafter during the term of this Purchase and Sale Agreement on any date prior to the Royalty Termination Date:

(a) the Royalties and the Milestone Payments; and

(b) all interest payments to the Seller in respect of the late payment of any of the amounts referred to in the foregoing clause (a) under Section 11.9(d) of the Commercialization Agreement.

"Purchaser" has the meaning set forth in the preamble.

- "Purchaser Account" has the meaning set forth in Section 5.4(b).
- "Purchaser Indemnified Party" has the meaning set forth in Section 7.1.
- "Purchaser Tax Forms" has the meaning set forth in Section 5.10(b).
- "Registrations" shall mean authorizations, approvals, licenses, permits, certificates, registrations, listings, or exemptions of or issued by any Governmental Authority (including Marketing Authorizations, investigational new drug applications, product recertifications, manufacturing approvals and authorizations, pricing and reimbursement approvals, labeling approvals or their foreign equivalent) that are required for the research, development, testing, manufacture, commercialization, distribution, marketing, export, import, storage, transportation, pricing, use and sale of the Product.
  - "Regulatory Authority" shall have the corresponding meaning as set forth in the Commercialization Agreement.
- "Related Agreements" means (a) the MSK Agreement, (b) the Ancillary Agreements (as defined under the MSK Agreement), (c) the Ancillary Agreements (as defined under the Commercialization Agreement), (d) the Manufacturing and Supply Agreement (if and when it becomes effective), (e) licenses by manufacturers and/or other vendors to intellectual property that is created or used in the course of services provided by such manufacturers or vendors, and (f) employment agreements, consulting agreements, clinical trial agreements, funding agreements, and other similar agreements entered into in the ordinary course.
- "Royalties" or "Royalty" means, for the period commencing on the Closing Date and thereafter during the term of this Purchase and Sale Agreement, all of the Seller's right, title and interest in and to:
- (a) the following royalty payments paid under Section 11.4 of the Commercialization Agreement in respect of Net Sales of the Product in the Territory made on or after the Closing Date:

[[\*\*\*]]

- (b) all amounts paid in lieu of the amounts described in clause (a); and
- (c) all payments paid under Section 11.10 of the Commercialization Agreement in respect of any underpayment of the amounts described in clause (a).
- For the avoidance of doubt, (i) the royalty rates provided in clause (a) above shall be subject to any Permitted Reductions actually taken, and (ii) Royalties shall include all amounts paid by one or more licensees or sublicensees under any New Arrangement.
- "Royalty Cap" means (a) [[\*\*\*]] 185% of the Purchase Price, (b) [[\*\*\*]]200% of the Purchase Price, and (c) [[\*\*\*]] 250% of the Purchase Price, in each case crediting towards the Royalty Cap any payments (i) payable to Purchaser in respect of the Purchased Royalties or (ii) actually received by Purchaser in respect of the Special Payment. For the avoidance of doubt, the aggregate payments payable to Purchaser [[\*\*\*]], as applicable, in respect to the Purchased Royalties shall be calculated and based on amounts arising on account of Net Sales billed or invoiced on or prior to such date.

"Royalty Reduction" has the meaning set forth in Section 3.10(h).

- "Royalty Report" shall have the corresponding meaning as set forth in the Commercialization Agreement.
- "Royalty Term" shall have the corresponding meaning as set forth in the Commercialization Agreement.
- "Royalty Termination Date" means the earliest of (a) the date on which aggregate payments of the Purchased Royalties actually received by the Purchaser (for the avoidance of doubt, including the Special Payment, if actually received by the Purchaser) equal the Royalty Cap applicable at such time or (b) the date of the last Royalty payment under the Commercialization Agreement. For purposes of this definition, the portion of any amount payable to the Purchaser under this Agreement that is deemed actually received by the Purchaser shall include any portion of such amount that is withheld in respect of any Taxes (other than Seller Action Taxes).
  - "SEC" means the U.S. Securities and Exchange Commission.
  - "Seller" has the meaning set forth in the preamble.
  - "Seller Account" has the meaning set forth in Section 5.4(d).
- "Seller Action Taxes" means any incremental amount of Taxes withheld or deducted from any payment of Purchased Royalties to the Purchaser arising solely as a result of any of the following actions taken by the Seller after the date hereof (i) a reincorporation or other action resulting in a change in its Tax residence or (ii) an assignment, delegation or transfer of its rights and obligations hereunder to another Person, other than at the request of the Purchaser.
  - "Seller Indemnified Party" has the meaning set forth in Section 7.2.
- "Set-Off" means any right of set-off, counterclaim, credit, reduction or deduction by contract or otherwise, other than a Permitted Reduction; provided, however, that "Set-Off" shall not include any Royalty Reduction or deduction, withholding, or set-off on account of Taxes.
  - "Special Payment" has the meaning set forth in Section 2.6.
- "Subsidiary" means, with respect to any Person, any other Person of which more than 50% of the outstanding voting securities of such other Person is at the time directly or indirectly owned or controlled by such Person, by such Person and one or more other Subsidiaries of such Person or by one or more other Subsidiaries of such Person, or such lesser amount of voting securities that is sufficient to enable such Person to elect at least a majority of the members of such entity's board of directors or other governing body. Unless otherwise specified, references to a "Subsidiary" or "Subsidiaries" in this Purchase and Sale Agreement shall refer to Atara Biotherapeutics Ireland Limited, and no other Subsidiary of Seller.
- "Tax" or "Taxes" means any U.S. federal, state, local or non-U.S. income, gross receipts, license, payroll, employment, excise, severance, occupation, premium, windfall profits, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, abandoned property, value added, alternative or add-on minimum, estimated or other tax of any kind whatsoever, including any interest, penalty or addition thereto, in each case, whether disputed or not.
- "Term" means, unless earlier terminated by a Party or the Parties herein, the time period between the Closing Date and the Royalty Termination Date.

- "Territory" shall have the corresponding meaning as set forth in the Commercialization Agreement.
- "Third Party" means any Person that is not a Party or an Affiliate of a Party.
- "Third-Party Claim" means any claim, action, suit or proceeding by a Third Party, including any investigation by any Governmental Authority.
- "Transaction Documents" means this Purchase and Sale Agreement, the Escrow Agreement, the Bill of Sale, and the Licensee Instruction.
- "<u>Transaction Expenses</u>" means the aggregate amount of any and all documented out-of-pocket fees and expenses reasonably incurred by or on behalf of, or paid directly by, the Purchaser in connection with the diligence of the transactions contemplated hereby, and the negotiation, preparation and execution of the Transaction Documents; provided, however, that the Transaction Expenses shall not exceed [[\*\*\*]].
- "<u>UCC</u>" means the Uniform Commercial Code as in effect from time to time in the State of New York; <u>provided</u> that, if, with respect to any financing statement or by reason of any provisions of law, the perfection or the effect of perfection or non-perfection of the security interests or any portion thereof granted pursuant to <u>Section 2.1</u> is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than the State of New York, then "<u>UCC</u>" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Purchase and Sale Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.
  - "U.S." or "United States" means the United States of America, its 50 states, each territory thereof and the District of Columbia.

## Section 1.2 Rules of Construction.

- (a) Unless the context otherwise requires, in this Purchase and Sale Agreement:
- (i) a term has the meaning assigned to it and an accounting term not otherwise defined has the meaning assigned to it in accordance with GAAP:
  - (ii) unless otherwise defined, all terms that are defined in the UCC shall have the meanings stated in the UCC;
  - (iii) words of the masculine, feminine or neuter gender shall mean and include the correlative words of other genders;
- (iv) the terms "include," "including" and similar terms shall be construed as if followed by the phrase "without limitation" and the terms "either" and "or" will be interpreted in the inclusive sense commonly associated with the term "and/or";
- (v) unless otherwise specified, references to a contract or agreement include references to such contract or agreement as amended, restated, reformed, supplemented or otherwise modified in accordance with its terms through the Effective Date, and include any annexes, exhibits and schedules hereto or thereto in effective as of the Effective Date;

- (vi) any reference to any Person shall be construed to include such Person's successors and assigns (subject to any restrictions on assignment, transfer or delegation set forth herein or in any of the other Transaction Document) and any reference to a Person in a particular capacity excludes such Person in other capacities;
- (vii) references to any Applicable Law shall include such Applicable Law as from time to time in effect, including any amendment, modification, codification, replacement, or reenactment thereof or any substitution therefor;
  - (viii) the word "will" shall be construed to have the same meaning and effect as the word "shall";
- (ix) the words "hereof," "herein," "hereunder" and similar terms shall refer to this Purchase and Sale Agreement as a whole and not to any particular provision hereof, and Article, Section and Exhibit references herein are references to Articles and Sections of, and Exhibits to, this Purchase and Sale Agreement unless otherwise specified;
  - (x) the definitions of terms shall apply equally to the singular and plural forms of the terms defined;
- (xi) in the computation of a period of time from a specified date to a later specified date, the word "from" means "from and including" and each of the words "to" and "until" means "to but excluding";
- (xii) where any payment is to be made, any funds are to be applied or any calculation is to be made under this Purchase and Sale Agreement on a day that is not a Business Day, unless this Purchase and Sale Agreement otherwise provides, such payment shall be made, such funds shall be applied and such calculation shall be made on the succeeding Business Day, and payments shall be adjusted accordingly; and
- (xiii) any reference to a term that is defined by reference to its meaning in the Commercialization Agreement shall refer to such term's meaning therein as in existence on the Effective Date (and not to any new, substituted or amended version thereof).
- (b) The provisions of this Purchase and Sale Agreement shall be construed according to their fair meaning and neither for nor against any Party irrespective of which Party caused such provisions to be drafted. Each Party acknowledges that it has been represented by an attorney in connection with the preparation and execution of this Purchase and Sale Agreement and the other Transaction Documents.

## ARTICLE II PURCHASE AND SALE OF THE PURCHASED ROYALTIES

## Section 2.1 Purchase and Sale.

(a) Subject to the terms and conditions of this Purchase and Sale Agreement, on the Closing Date, the Seller hereby sells, assigns, transfers, conveys and grants to the Purchaser, and the Purchaser hereby purchases, acquires and accepts from the Seller, all of the Seller's rights, title and interest in and to the Purchased Royalties, free and clear of any and all Liens, other than any Liens under clauses (i) through (vi), inclusive, of the definition of Permitted Liens. Immediately upon the sale to the Purchaser by Seller of the Purchased Royalties pursuant to this Section 2.1, all of Seller's right, title and

interest in and to the Purchased Royalties shall terminate, and all such right, title and interest shall vest in the Purchaser.

- (b) Subject to the terms and conditions of this Purchase and Sale Agreement, the Seller and the Purchaser intend and agree that the sale, assignment, transfer, conveyance and granting of the Purchased Royalties under this Purchase and Sale Agreement shall be, and are, a true, complete, absolute and irrevocable assignment, conveyance, grant, sale and transfer by the Seller to the Purchaser of all of the Seller's right, title and interest in and to the Purchased Royalties and that such assignment, conveyance, grant, sale and transfer shall provide the Purchaser with the full benefits of ownership of the Purchased Royalties as of the Closing Date. Neither the Seller nor the Purchaser intends the transactions contemplated hereby to be, or for any purpose (other than for accounting purposes) characterized as, a loan from the Purchaser to the Seller or a pledge, a security interest, a financing transaction, or a borrowing. It is the intention of the Parties that the beneficial interest in and title to the Purchased Royalties and any "proceeds" (as such term is defined in the UCC) thereof shall not be part of the Seller's estate in the event of the filing of a petition by or against Seller in connection with any Bankruptcy Event. Each of the Seller and the Purchaser hereby waives, to the maximum extent permitted by Applicable Law, any right to contest or otherwise assert that this Purchase and Sale Agreement does not constitute a true, complete, absolute and irrevocable assignment, conveyance, grant, sale and transfer by the Seller to the Purchaser of all of the Seller's right, title and interest in and to the Purchased Royalties under Applicable Law, which waiver shall, to the maximum extent permitted by Applicable Law, be enforceable against the Seller in any Bankruptcy Event in respect of the Seller. Accordingly, the Seller shall treat the assignment, conveyance, sale and transfer of the Purchased Royalties as a sale of an "account" or a "payment intangible" (as appropriate) in accordance with the UCC.
- (c) The Seller hereby authorizes the Purchaser, from and after the Closing, to execute, record and file, and consents to the Purchaser executing, recording and filing, at the Purchaser's sole cost and expense, financing statements in the appropriate filing offices under the UCC (and continuation statements or amendments with respect to such financing statements when applicable), naming the Seller as the debtor/seller and the Purchaser as the secured party/buyer in respect of the Purchased Royalties, in such manner and in such jurisdictions as are necessary or appropriate to evidence or perfect the sale, assignment, conveyance, grant, sale and transfer by the Seller to the Purchaser, and the purchase, acquisition and acceptance by the Purchaser from the Seller, of the Purchased Royalties and to perfect the security interest in the Purchased Royalties granted by the Seller to the Purchaser pursuant to Section 2.1(d)
- (d) Notwithstanding that the Seller and the Purchaser expressly intend for the sale, assignment, transfer, conveyance and granting of the Purchased Royalties to be a true, complete, absolute and irrevocable sale and assignment, and for the purposes of providing additional assurance to the Purchaser, the Seller hereby assigns, conveys, grants and pledges to the Purchaser, from and after the Closing, subject to the terms and conditions of this Purchase and Sale Agreement, as security for its obligations created hereunder in the event that the transfer contemplated by this Purchase and Sale Agreement is held not to be a sale, a first priority security interest in and to all of the Seller's right, title and interest in, to and under the Purchased Royalties and, in such event, this Purchase and Sale Agreement shall constitute a security agreement

Section 2.2 <u>Purchase Price</u>. In full consideration for the sale, assignment, transfer, conveyance and granting of the Purchased Royalties, and subject to the terms and conditions set forth herein, the Purchaser shall pay (or cause to be paid) to the Seller, the sum of \$31,000,000 in cash (the "<u>Purchase Price</u>"), without any deduction or withholding on account of any Taxes, within 15 Business Days after Purchaser receives notice from Seller in accordance with <u>Section 5.1(f)</u> of this Agreement of grant of centralized Marketing Authorization in the European Union by the European Commission of the Product

for the treatment of EBV+ PTLD; provided that such centralized Marketing Authorization in the European Union occurs no later than 5:00 p.m. (Eastern Time) on December 31, 2022. Notwithstanding the foregoing, the Purchaser may at any time in its sole discretion waive any or all conditions to payment of all or any portion of the Purchase Price.

Section 2.3 No Assumed Obligations. Notwithstanding any provision in this Purchase and Sale Agreement or any other writing to the contrary, the Purchaser is purchasing, acquiring and accepting only the Purchased Royalties and is not assuming any liability or obligation of the Seller or any of the Seller's Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, including any liability or obligation of the Seller under the Commercialization Agreement or any Related Agreement. All such liabilities and obligations shall be retained by, and remain liabilities and obligations of, the Seller or the Seller's Affiliates, as the case may be (the "Excluded Liabilities and Obligations").

Section 2.4 Excluded Assets. The Purchaser does not, by purchase, acquisition or acceptance of the right, title or interest granted hereunder or otherwise pursuant to any of the Transaction Documents, purchase, acquire or accept any assets or contract rights of the Seller under the Commercialization Agreement, other than the Purchased Royalties, or any other assets of the Seller.

Section 2.5 <u>Buyout Option</u>. The Seller may, at its option, make a payment at any time, upon providing [[\*\*\*]] Business Days prior written notice to the Purchaser, equal to the difference between (a) the applicable Royalty Cap at such time and (b) the aggregate amount of payments paid to the Purchaser under this Purchase and Sale Agreement at such time. If the Seller makes such payment to the Purchaser then the Royalty Termination Date shall be deemed to have occurred, and this Purchase and Sale Agreement shall terminate pursuant to <u>Section 9.1</u>.

Section 2.6 <u>Special Payment</u>. If [[\*\*\*]] has not been achieved on or prior to [[\*\*\*]], then within [[\*\*\*]] (i.e. no later than [[\*\*\*]]) (or within [[\*\*\*]] of the date (if earlier than [[\*\*\*]]) any Party receives notice that [[\*\*\*]] will not be achieved prior to [[\*\*\*]]) Seller shall make a one-time cash payment to Purchaser in the amount of \$9,000,000 (the "<u>Special Payment</u>"). If the Special Payment is made, in consideration for the Special Payment the Purchaser shall transfer all of its right, title and interest in the [[\*\*\*]] to Seller, and shall take such actions as Seller reasonably requests (at Purchaser's sole expense) to evidence such transfer, including entering into a bill of sale.

# ARTICLE III REPRESENTATIONS AND WARRANTIES OF THE SELLER

Except as set forth on the Disclosure Schedule, the Seller hereby makes each of the following representations and warranties to the Purchaser, as of the date hereof, as follows:

Section 3.1 <u>Organization</u>. The Seller is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware and has all corporate power and authority, and all licenses, permits, franchises, authorizations, consents and approvals of all Governmental Authorities, required to own its property and conduct its business, as now conducted, in all material respects. The Seller is duly licensed or qualified to transact business and is in good standing in every jurisdiction in which such licensing or qualification or standing is required by Applicable Law (except where the failure to be so licensed or qualified or in good standing would not reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect).

Section 3.2 <u>Authorization</u>. The Seller has all necessary corporate power and authority to execute and deliver the Transaction Documents, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of each of

the Transaction Documents and the performance by the Seller of its obligations hereunder and thereunder have been duly authorized by all necessary corporate action on the part of the Seller. Each of the Transaction Documents has been duly executed and delivered by an authorized officer of the Seller. Each of the Transaction Documents constitutes the legal, valid and binding obligation of the Seller, enforceable against the Seller in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and general equitable principles.

Section 3.3 No Conflicts. The execution and delivery by the Seller of any of the Transaction Documents, the performance by the Seller of its obligations hereunder or thereunder, and the consummation by the Seller of the transactions contemplated hereby or thereby will not (i) contravene, conflict with or violate any term or provision of any of the organizational documents of the Seller or any of its Subsidiaries, (ii) except as would not reasonably be expected to have a Material Adverse Effect, contravene, conflict with or violate, or give any Governmental Authority or other Person the right to exercise any remedy or obtain any relief under, any Applicable Law or any judgment, order, writ, decree, permit or license of any Governmental Authority to which the Seller or any of its Subsidiaries or any of their respective assets or properties may be subject or bound, (iii) result in a breach or violation of, constitute a default (with or without notice or lapse of time, or both) under, or give any Person the right to exercise any remedy or obtain any additional rights under, or accelerate the maturity or performance of, or payment under, or cancel or terminate, (A) except as would not reasonably be expected to have a Material Adverse Effect, any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which the Seller or any of its Subsidiaries is a party or by which the Seller or any of its Subsidiaries or any of their respective assets or properties is bound or committed (other than the Commercialization Agreement or the MSK Agreement) or (B) the Commercialization Agreement or the MSK Agreement, or (iv) except as provided in any of the Transaction Documents, result in or require the creation or imposition of any Lien on the Intellectual Property Rights, the Commercialization Agreement, the MSK Agreements or the Purchased Royalties.

Section 3.4 Ownership. The Seller is the exclusive owner of the entire right, title (legal and equitable) and interest in, to and under the Purchased Royalties. The Purchased Royalties sold, assigned, transferred, conveyed and granted to the Purchaser on the Closing Date have not been pledged, sold, assigned, transferred, conveyed or granted by the Seller to any other Person. The Seller has full right to sell, assign, transfer, convey and grant the Purchased Royalties to the Purchaser. Upon the sale, assignment, transfer, conveyance and granting by the Seller of the Purchased Royalties to the Purchaser, the Purchaser shall acquire good and marketable title to the Purchased Royalties free and clear of all Liens, other than any Liens under clauses (i) through (vi), inclusive, of the definition of Permitted Liens, and shall be the exclusive owner of the Purchased Royalties.

Section 3.5 Governmental and Third Party Authorizations. The execution and delivery by the Seller of the Transaction Documents, the performance by the Seller of its obligations hereunder and thereunder, and the consummation by the Seller of the transactions contemplated hereby and thereby do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by, or filing with, any Governmental Authority or any other Person, except for (i) the filing of a Current Report on Form 8-K with the SEC, (ii) the filing of the UCC financing statements contemplated by Section 2.1, (iii) those previously obtained, (iv) the notice to Licensee contained in the Licensee Instruction, and (v) such consents, the failure of which to be obtained or made, would not reasonably be expected to have a Material Adverse Effect.

Section 3.6 No Litigation. There is no action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, inquiry, investigation, or other proceeding (whether civil, criminal, administrative, regulatory or informal) by or before any Governmental Authority (a) pending or, to the

Knowledge of the Seller, threatened by or against the Seller or any of its Subsidiaries that would have a Material Adverse Effect or (b) except for routine maintenance and prosecution and routine regulatory proceedings, pending against the Seller or, to the Knowledge of the Seller, pending or threatened by or against Licensee, its Affiliates, any of its sublicensees, or MSK, in each case under this clause (b) in respect of the Commercialization Agreement, the Manufacturing and Supply Agreement, the MSK Agreement, the Intellectual Property Rights, the Product or the Purchased Royalties, at law or in equity. To the Knowledge of the Seller, no event has occurred or circumstance exists that would reasonably be expected to give rise to or serve as a basis for the commencement of any such action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, inquiry, investigation, or other proceeding.

Section 3.7 No Brokers' Fees. The Seller has not taken any action that would entitle any person or entity to any commission or broker's fee in connection with the transactions contemplated by this Purchase and Sale Agreement.

Section 3.8 <u>Compliance with Laws</u>. None of the Seller or any of its Subsidiaries (a) has violated or is in violation of, has been given written notice of any violation of, or, to the Knowledge of the Seller, is under investigation with respect to or has been threatened to be charged with, any violation of, any Applicable Law or any judgment, order, writ, decree, injunction, stipulation, consent order, permit or license granted, issued or entered by any Governmental Authority or (b) is subject to any judgment, order, writ, decree, injunction, stipulation or consent order issued or entered by any Governmental Authority, in each case (a) and (b), that would have, individually or in the aggregate, a Material Adverse Effect.

### Section 3.9 Intellectual Property Matters.

- (a) Schedule 3.9 sets forth an accurate and complete list of all issued patents and pending patent applications within the Licensed Patents as of the Effective Date. For each Licensed Patent listed on Schedule 3.9 the Seller has indicated (i) the countries in which such Licensed Patent is pending, allowed, granted or issued, (ii) the patent number or patent application serial number, (iii) the issue or filing date of each such issued Licensed Patent, and (iv) the owner thereof. Except as set forth on Schedule 3.9, Seller is the sole owner of, and has the sole interest in, all of the Licensed Patents.
- (b) There are no unpaid maintenance or renewal fees payable by the Seller to any Third Party that currently are overdue for any of the Licensed Patents. No Licensed Patents have lapsed or been abandoned, cancelled or expired, except for any such Licensed Patents abandoned pursuant to the exercise of reasonable judgment and in the ordinary course of business. Each of the issued Licensed Patents listed on Schedule 3.9 is in full force and effect and, to the Knowledge of the Seller, is valid and enforceable. To the Knowledge of the Seller, each individual associated with the filing and prosecution of the Licensed Patents, including the named inventors of the Licensed Patents, has complied in all material respects with all applicable duties of candor and good faith in dealing with any Patent Office, including any duty to disclose to any Patent Office all information known by such inventors to be material to the patentability of the Licensed Patents (including any relevant prior art), in each case, in those jurisdictions in the Territory where such duties exist.
- (c) (i) There is no pending or, to the Knowledge of the Seller, threatened opposition, interference, reexamination, post-grant review or similar administrative proceedings, injunction, claim, suit, action, citation, summon, subpoena, complaint, arbitration, mediation, demand, decree or other dispute, disagreement, proceeding or claim to which Seller is a party or, to the Knowledge of the Seller, to which MSK is a party, and (ii) to the Knowledge of the Seller, there is no pending or threatened hearing, inquiry or investigation (by the International Trade Commission or any other Governmental Authority) (collectively, (i) and (ii), "Disputes"), in each case of (i) and (ii) challenging the legality, validity, scope, enforceability or ownership of any of the Licensed Patents, other than routine maintenance and

prosecution of the Licensed Patents, or that would give rise to any Royalty Reduction against the payments due to the Seller under the Commercialization Agreement. The Licensed Patents owned by the Seller, and, to the Knowledge of the Seller, the other Intellectual Property Rights, are not subject to any outstanding injunction, judgment, order, decree, ruling, settlement or other disposition of a Dispute.

- (d) There is no pending or, to the Knowledge of the Seller, threatened action, suit, proceeding, governmental investigation, or claim to which the Seller or any of its Affiliates is a party nor, to the Knowledge of the Seller, to which Licensee is a party, by any Person that claims that the manufacture, use, marketing, sale, offer for sale, importation or distribution of the Product does or will infringe on any issued patent or other intellectual property rights of any Third Party or constitute misappropriation of any other Person's trade secrets or other intellectual property rights. To the Knowledge of Seller, there are no issued patents owned by a Third Party that would be infringed by the manufacture, use, marketing, sale, offer for sale, importation or distribution of the Product in the Territory.
- (e) To the Knowledge of the Seller, there is no Person infringing any of the Intellectual Property Rights, nor has the Seller received any written notice under the Commercialization Agreement of infringement of any of the Intellectual Property Rights.
- (f) The Seller and, to the Knowledge of the Seller, Licensee has taken commercially reasonable precautions to protect the confidentiality of the Know-How that is comprised in the Intellectual Property Rights.
- (g) The Intellectual Property Rights constitute all of the intellectual property owned or licensed by the Seller or any of the Seller's Affiliates that, to the Seller's Knowledge, would be infringed by the use, making, sale, offer for sale or importation of the Product in the Field in the Territory.
- (h) To the Knowledge of the Seller, there is no Person who is or claims to be an inventor under any Licensed Patent who is not a named inventor thereof.

## Section 3.10 Counterparty Agreements.

- (a) Attached as Exhibit D and Exhibit E are true, correct and complete copies of the Commercialization Agreement and the MSK Agreement, respectively. The Seller has provided to the Purchaser true, correct and complete copies of all material notices delivered to the Seller by the Licensee or by the Seller to the Licensee since October 2, 2021 pursuant to, or relating to, the Commercialization Agreement and the MSK Agreement, respectively.
- (b) Other than the Transaction Documents, the Related Agreements, the Commercialization Agreement, the Existing Confidentiality Agreement, and any Liens under clauses (vii), (viii), (x) and (xi) of the definition of Permitted Liens, there is no contract, agreement or other arrangement (whether written or oral) to which the Seller or any of its Subsidiaries is a party that affects or otherwise relates to the Purchased Royalties, the Commercialization Agreement or the Intellectual Property Rights.
- (c) The Commercialization Agreement is in full force and effect and is the legal, valid and binding obligation of the Seller and the Licensee, enforceable against the Seller and the Licensee in accordance with its terms, subject, as to enforceability, to bankruptcy, insolvency, reorganization, moratorium or similar laws now or hereafter in effect relating to or affecting creditors' rights generally, and general equitable principles. The Seller is not in breach or violation of or in default in any material respect under the Commercialization Agreement. To the Knowledge of the Seller, there is no event or

circumstance that, upon notice or the passage of time, or both, would constitute or give rise to any material breach or material default in the performance of the Commercialization Agreement by the Seller or the Licensee.

- (d) The MSK Agreement is in full force and effect and is the legal, valid and binding obligation of the Seller and MSK, enforceable against the Seller and MSK in accordance with its terms, subject, as to enforceability, to bankruptcy, insolvency, reorganization, moratorium or similar laws now or hereafter in effect relating to or affecting creditors' rights generally, and general equitable principles. The Seller is not in breach or violation of or in default in any material respect under the MSK Agreement. To the Knowledge of the Seller, there is no event or circumstance that, upon notice or the passage of time, or both, would constitute or give rise to any material breach or material default in the performance of the MSK Agreement by the Seller or MSK.
- (e) The Seller has not (i) waived any material rights or defaults under the Commercialization Agreement, or released the Licensee, in whole or in part, from any of its material obligations under the Commercialization Agreement, that relate to the Development and Commercialization of the Product in the Field in the Territory or the Purchased Royalties, and (ii) waived any other rights or defaults under the Commercialization Agreement, or released the Licensee, in whole or in part, from any of its other obligations under the Commercialization Agreement except for such waivers and releases that would not reasonably be expected to have a Material Adverse Effect. Except in connection with the negotiation of the terms and conditions of the Amendment, the Seller has not received from Licensee any written proposal, and has not made any proposal to the Licensee, to amend or waive any provision of the Commercialization Agreement.
- (f) The Seller has not exercised its rights to conduct an audit under the Commercialization Agreement. To the Knowledge of the Seller, no event has occurred that would give the Seller or the Licensee the right to terminate the Commercialization Agreement or cease paying the Purchased Royalties under the Commercialization Agreement. The Seller has not received any written notice of an intention by the Licensee to terminate or breach the Commercialization Agreement, in whole or in part, or challenging the validity or enforceability of the Commercialization Agreement or the obligation to pay the Purchased Royalties under the Commercialization Agreement, or alleging that the Seller or the Licensee is currently in default of its obligations under the Commercialization Agreement. To the Knowledge of the Seller, there is and has been no default, violation or breach by the Licensee under the Commercialization Agreement. Neither the Seller nor the Licensee has made any claim of indemnification under the Commercialization Agreement. The Seller has no intention of terminating the Commercialization Agreement and has not given the Licensee any notice of termination of the Commercialization Agreement, in whole or in part.
- (g) To the Knowledge of the Seller, no event has occurred that would give MSK the right to terminate the MSK Agreement. The Seller has not received any written notice of an intention by MSK to terminate or breach the MSK Agreement, in whole or in part, or challenging the validity or enforceability of the MSK Agreement, or alleging that the Seller is currently in default of its obligations under the MSK Agreement. To the Knowledge of the Seller, there is and has been no default, violation or breach by MSK under the MSK Agreement. Neither the Seller nor MSK has made any claim of indemnification under the MSK Agreement. The Seller has no intention of terminating the MSK Agreement and has not given MSK any notice of termination of the MSK Agreement, in whole or in part with respect to the Territory.
- (h) Except as provided in the Commercialization Agreement, the Seller is not a party to any agreement providing for any sharing of, or providing for or permitting any right of counterclaim,

credit, reduction or deduction by contract or otherwise (a "Royalty Reduction") or permitting any Set-Off against, the Royalties.

(i) The Seller has not consented to an assignment by the Licensee of any of its rights or obligations under the Commercialization Agreement, and the Seller does not have Knowledge of any such assignment by the Licensee. Except for Permitted Liens and as contemplated by the Transaction Documents, the Seller has not assigned, in whole or in part, and has not granted, incurred or suffered to exist any Lien on, the Commercialization Agreement, the MSK Agreement or any of the Seller's rights, title or interest in or to the Intellectual Property Rights. Except for the Related Agreements, any Liens under clauses (vii), (viii), (x), and (xi) of the definition of Permitted Liens, to the Knowledge of the Seller, there are no licenses, sublicenses or other rights under the Intellectual Property Rights that have been granted to any Third Party.

Section 3.11 <u>UCC Matters</u>. The Seller's exact legal name is, and for the preceding five years has been, "Atara Biotherapeutics, Inc." The Seller's principal place of business is, and for the preceding five years has been, located in the State of California. The Seller's jurisdiction of organization is, and for the preceding five years has been, the State of Delaware. For the preceding five years, the Seller has not been the subject of any merger or other reorganization in which its legal name or status was materially changed, except in each case where it was the surviving or resulting Person.

Section 3.12 <u>Set-off and Other Sources of Royalty Reduction</u>. The Licensee has not exercised, and, to the Knowledge of the Seller, the Licensee has not had the right to exercise, and, to the Knowledge of the Seller, no event or condition exists that, upon notice or passage of time, or both, would permit the Licensee to exercise, any Royalty Reduction or Set-Off against the Royalties or any other amounts payable to the Seller under the Commercialization Agreement. To the Knowledge of the Seller, there are no Third Party Patent Rights (as defined in the Commercialization Agreement) that would provide a basis for a Royalty Reduction.

Section 3.13 <u>Solvency</u>. Immediately after giving effect to the consummation of the transactions contemplated by the Transaction Documents and the application of the proceeds therefrom, (a) the fair value of the Seller's assets will be greater than the sum of its debts, liabilities and other obligations, including contingent liabilities, (b) the Seller will not have become subject to any Bankruptcy Event and (c) the Seller will not have been rendered insolvent within the meaning of Section 101(32) of Title 11 of the Bankruptcy Code. For purposes of this Section 3.13, the amount of all contingent obligations at any time shall be computed as the amount that, in light of all facts and circumstances existing at such time, can reasonably be expected to become an actual or matured liability.

Section 3.14 <u>Manufacturing</u>. The final, finished and released form of the Product has, [[\*\*\*]], been manufactured, transported, stored and handled in all material respects in accordance with Applicable Law and with GMP. [[\*\*\*]].

## Section 3.15 Regulatory Compliance.

(a) The Seller has all Registrations from the EMA, the European Commission and Regulatory Authorities of EU Member States or any other applicable Governmental Authority in the Territory required to conduct its business as currently conducted with respect to the Product and its obligations under the Commercialization Agreement and the Manufacturing and Supply Agreement to the extent such obligations arose as of the date hereof. Each of such material Registrations is subsisting in full force and effect, and, to the Knowledge of the Seller, is valid. All applications, submissions, information and data with respect to the Product that (i) is intended to be or was provided to a Regulatory Authority in

the Territory, or (ii) was provided by the Seller to Licensee, was true and correct and generated in compliance with Applicable Laws in all material respects.

- (b) In the course of the development of Product, the Seller 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 the Seller's knowledge, no such employees or consultants have been used by any Third Party on behalf of the Seller in connection with the development of the Product.
- (c) All studies conducted by or on behalf of the Seller with respect to the Product in the Territory have been conducted in accordance with Applicable Laws in all material respects by persons with appropriate education, knowledge and experience in all material respects.
- (d) The Seller has provided to the Purchaser true and correct copies or summaries of all material written communications sent or received by Seller and any of its Affiliates to or from any Regulatory Authorities in the Territory that relate to the Product and the Field since January 1, 2022.

Section 3.16 <u>Taxes</u>. No deduction or withholding for or on account of any Tax has been made or, to the knowledge of Seller, was required to have been made in respect of any amounts actually paid (or due and payable as of the date hereof) to Seller under the Commercialization Agreement.

# ARTICLE IV REPRESENTATIONS AND WARRANTIES OF THE PURCHASER

The Purchaser, hereby represents and warrants to the Seller, as of the date hereof, as follows:

Section 4.1 <u>Organization</u>. The Purchaser is a limited liability partnership duly organized, validly existing and in good standing under the laws of Delaware.

Section 4.2 <u>Authorization</u>. The Purchaser has all necessary limited partnership power and authority to execute and deliver the Transaction Documents to which the Purchaser is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of each of the Transaction Documents to which the Purchaser is party and the performance by the Purchaser of its obligations hereunder and thereunder have been duly authorized by the Purchaser. Each of the Transaction Documents to which the Purchaser is party has been duly executed and delivered by the Purchaser. Each of the Transaction Documents to which the Purchaser is party constitutes the legal, valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with its respective terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally, and general equitable principles.

Section 4.3 No Conflicts. The execution and delivery by the Purchaser of any of the Transaction Documents to which the Purchaser is party, the performance by the Purchaser of its obligations hereunder or thereunder or the consummation by the Purchaser of the transactions contemplated hereby or thereby will not (i) contravene, conflict with or violate any term or provision of any of the organizational documents of the Purchaser, (ii) except as would not reasonably be expected to have a Material Adverse Effect, contravene, conflict with or violate, or give any Governmental Authority or other Person the right to exercise any remedy or obtain any relief under, in any material respect, any Applicable Law or any judgment, order, writ, decree, permit or license of any Governmental Authority to which the Purchaser or any of its assets or properties may be subject or bound or (iii) result in a breach or violation of, constitute a default (with or without notice or lapse of time, or both) under, or give any

Person any right to exercise any remedy or obtain any additional rights under, or accelerate the maturity or performance of or payment under, or cancel or terminate, except as would not reasonably be expected to have a Material Adverse Effect, any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which the Purchaser is a party or by which the Purchaser or any of its assets or properties is bound or committed.

Section 4.4 <u>Governmental and Third Party Authorizations</u>. The execution and delivery by the Purchaser of the Transaction Documents to which the Purchaser is party, the performance by the Purchaser of its obligations hereunder and the consummation of the transactions contemplated hereby and thereby do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by, or filing with, any Governmental Authority or any other Person, except for (i) the filing of the UCC financing statements contemplated by <u>Section 2.1</u>, (ii) those previously obtained, (iii) the notice to Licensee contained in the Licensee Instruction, and (iv) such consents, the failure of which to be obtained or made, would not reasonably be expected to have a Material Adverse Effect.

Section 4.5 No Litigation. There is no (a) action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal) pending or, to the knowledge of the Purchaser, threatened by or against the Purchaser, at law or in equity, or (b) inquiry or investigation (whether civil, criminal, administrative, regulatory, investigative or informal) by or before a Governmental Authority pending or, to the knowledge of the Purchaser, threatened against the Purchaser, that, in any case challenges or seeks to prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents.

Section 4.6 <u>Access to Information</u>. The Purchaser acknowledges that it has reviewed the Commercialization Agreement and such other documents and information relating to, and has had the opportunity to ask such questions of, and to receive answers from, representatives of the Seller concerning, the Product, the Intellectual Property Rights, the Commercialization Agreement, the Purchased Royalties, and any other matter relating thereto, in each case, as it deemed necessary to make an informed decision to purchase, acquire and accept the Purchased Royalties in accordance with the terms of this Purchase and Sale Agreement. Except as specifically set forth in this <u>ARTICLE III</u> and the Disclosure Schedules, the Purchaser acknowledges and agrees that the Seller makes no representation nor extends any warranty, whether express or implied, with respect to the Product, the Intellectual Property Rights, the Commercialization Agreement, the Purchased Royalties, or any other matter relating thereto. The Purchaser has such knowledge, sophistication and experience in financial and business matters that it is capable of evaluating the risks and merits of purchasing, acquiring and accepting the Purchased Royalties in accordance with the terms of this Purchase and Sale Agreement. Notwithstanding the foregoing, claims for fraud shall not be waived or limited in any way by this <u>Section 4.6</u>.

Section 4.7 <u>Funds Available</u>. The Purchaser has sufficient cash on hand or capital commitments to satisfy its obligation to pay the Purchase Price if and as such payment becomes payable in accordance with <u>Section 2.2</u>. The Purchaser's obligations under this Purchase and Sale Agreement are not contingent on obtaining financing.

ARTICLE V COVENANTS

The Parties covenant and agree as follows:

Section 5.1 Notices.

(a) Following the completion of each Calendar Quarter during the term of this Purchase and Sale Agreement, as promptly as practicable, but in any event no later than [[\*\*\*]] Business Days after the Seller receives a Royalty Report for such Calendar Quarter, the Seller shall deliver to the Purchaser a true, correct and complete copy of each Royalty Report (other than any preliminary, non-binding, estimated Royalty Reports) in respect of such completed Calendar Quarter.

- (b) Promptly (but in no event more than [[\*\*\*]] Business Days) after receipt by the Seller of any material written notice from Licensee delivered under the Commercialization Agreement that relates to the Purchased Royalties or the Product in the Territory or that relates to matters that would reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect, the Seller shall either (i) to the extent not prohibited by obligations of confidentiality contained in the Commercialization Agreement, furnish the Purchaser with a copy of the written notice and any materials reasonably related thereto, provided that the Seller may redact any information that does not relate to the Purchased Royalties and the Product in the Territory and would not reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect, or (ii) notify the Purchaser in writing of the receipt of such written notice and provide the Purchaser with a written summary of all material details thereof. Except for the Licensee Instruction, the Seller shall not, except as Mutually Agreed, deliver any material written notice to the Licensee under the Commercialization Agreement that relates to the Purchased Royalties or the Product in the Territory or that would reasonably be expected (with or without the giving of notice or passage of time, or both) to result in a Material Adverse Effect. The Seller shall, promptly (and in any event no later than [[\*\*\*]] Business Days) following the delivery thereof by the Seller to the Licensee, furnish a copy of such material written notice, provided that the Seller may redact any information that is not related to the Purchased Royalties and the Product in the Territory and would not reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect.
- (c) Promptly (but in no event more than [[\*\*\*]] Business Days) after receipt by the Seller of any material written notice from MSK delivered under the MSK Agreement that relates to the Product in the Territory or that relates to matters that would reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect, the Seller shall either (i) to the extent not prohibited by obligations of confidentiality contained in the MSK Agreement, furnish the Purchaser with a copy of the written notice and any materials reasonably related thereto, provided that the Seller may redact any information that does not relate to the Product in the Territory and would not reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect, or (ii) notify the Purchaser in writing of the receipt of such written notice and provide the Purchaser with a written summary of all material details thereof. The Seller shall not, except as Mutually Agreed, deliver any material written notice to MSK under the MSK Agreement that relates to the Product in the Territory or that would reasonably be expected (with or without the giving of notice or passage of time, or both) to result in a Material Adverse Effect. The Seller shall, promptly (and in any event no later than [[\*\*\*]] Business Days) following the delivery thereof by the Seller to MSK, furnish a copy of such material written notice, provided that the Seller may redact any information that is not related to the Product in the Territory and would not reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect.

(d) The Seller shall provide the Purchaser with written notice as promptly as practicable (and in any event within [[\*\*\*]] Business Days) after obtaining Knowledge of any of the following: (i) the occurrence of any Bankruptcy Event in respect of the Seller, Atara Biotherapeutics Ireland Limited, or Licensee; (ii) any material breach or material default by the Seller of or under any material covenant, agreement or other provision of any Transaction Document; (iii) the Seller, Licensee or any other Third Party receiving any material written notice of audit or regulatory action by the European Commission, Regulatory Authorities of EU Member States or any other Government Authority

in the Territory relating to any of the Products or the Purchased Royalties; (iv) any representation or warranty made by the Seller in this Purchase and Sale Agreement (or in any certificate delivered by the Seller to the Purchaser pursuant to this Purchase and Sale Agreement or any of the other Transaction Documents) shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made; or (v) the occurrence or existence of any change, effect, event, occurrence, state of facts, development or condition that has had, or would have, a Material Adverse Effect.

- (e) The Seller shall notify the Purchaser in writing not less than [[\*\*\*]] Business Days prior to any change in, or amendment or alteration of, the Seller's (i) legal name, (ii) form or type of organizational structure or (iii) jurisdiction of organization.
- (f) The Seller shall notify Purchaser in writing within [[\*\*\*]] Business Days after receipt of centralized Marketing Authorization in the European Union of the Product for the treatment of EBV+ PTLD by the European Commission.

Section 5.2 <u>Public Announcement</u>. No Party shall, and each Party shall cause its Affiliates not to, without the prior written consent of the other Parties (which consent shall not be unreasonably withheld or delayed, and in the case of Seller, only the consent of the Purchaser shall be required), issue any press release or make any other public disclosure with respect to this Purchase and Sale Agreement or any of the other Transaction Documents or any of the transactions contemplated hereby or thereby, except if and to the extent that any such release or disclosure is required by Applicable Law, by the rules and regulations of any securities exchange or market on which any security of such Party may be listed or traded, or by any Governmental Authority of competent jurisdiction, in which case, the Party proposing to issue such press release or make such public disclosure shall, to the extent reasonably practicable, (a) provide the other Parties a copy of such proposed release or disclosure and (b) consider in good faith any comments or changes that the other Parties may propose or suggest; <u>provided</u> that a Party may freely make any public disclosure identical to a disclosure previously reviewed by the other Parties in accordance with the foregoing clauses (a) and (b). Notwithstanding the foregoing, the Purchaser understands and agrees that the Seller intends to file with the SEC a Current Report on Form 8-K, or to another filing with the SEC, describing the material terms of the transactions contemplated by this Purchase and Sale Agreement and the other Transaction Documents and some or all of the Transaction Documents as exhibits thereto, <u>provided</u> that the Seller shall (a) provide to the Purchaser a draft of such filings with the SEC and (b) consider in good faith any comments or changes that the Purchaser may propose or suggest. The Seller and the Purchaser shall jointly prepare a press release for dissemination promptly following the Closing, such press release to be agreed upon by the Purchaser and the

#### Section 5.3 <u>Further Assurances</u>.

(a) Subject to the terms and conditions of this Purchase and Sale Agreement, each Party shall execute and deliver such other documents, certificates, instruments, agreements and other writings, take such other actions and perform such additional acts under Applicable Law, subject to the applicable terms and conditions of the Commercialization Agreement, as may be reasonably requested by the other Party and necessary to implement expeditiously the transactions contemplated by, and to carry out the purposes and intent of the provisions of, this Purchase and Sale Agreement and the other Transaction Documents, including to (i) perfect the sale, assignment, transfer, conveyance and granting of the Purchased Royalties to the Purchaser pursuant to this Purchase and Sale Agreement, (ii) perfect, protect, more fully evidence, vest and maintain in the Purchaser good, valid and marketable rights and interests in and to the Purchased Royalties free and clear of all Liens (other than any Liens under clauses (i) through (vi), inclusive, of the definition of Permitted Liens), (iii) create, evidence and perfect the Purchaser's security interests granted pursuant to Section 2.1 and (iv) enable the Purchaser to exercise or enforce any of the Purchaser's rights under any Transaction Document to which the Purchaser is party.

- (b) The Seller and the Purchaser shall cooperate and provide assistance as reasonably requested by the other Party, at the expense of such other Party (except as otherwise set forth herein), in connection with any litigation, arbitration, investigation or other proceeding (whether threatened, existing, initiated or contemplated prior to, on or after the Closing Date) to which the other Party, any of its Affiliates or controlling persons or any of their respective officers, directors, managers, employees or controlling persons is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interest, in each case relating to any Transaction Document, the transactions contemplated hereby or thereby or the Purchased Royalties, but in all cases excluding any litigation brought by the Seller (for itself or on behalf of any Seller Indemnified Party) against the Purchaser or brought by the Purchaser (in each case, for itself or on behalf of any Purchaser Indemnified Party) against the Seller.
- (c) Each Party shall use its commercially reasonable efforts to comply with all Applicable Laws with respect to the Transaction Documents and the Purchased Royalties, except where compliance therewith is being contested by the such Party in good faith by appropriate proceedings.
- (d) The Seller shall not enter into any contract, agreement or other legally binding arrangement (whether written or oral), or grant any right to any other Person, in any case that would conflict with the Transaction Documents or serve or operate to limit, circumscribe or alter any of the Purchaser's rights under the Transaction Documents (or the Purchaser's ability to exercise any such rights).

# Section 5.4 Payments on Account of the Purchased Royalties.

- (a) If, notwithstanding the terms of the Licensee Instruction and the Escrow Agreement, the Licensee, any of its Affiliates, any of its sublicensees, or any other Person makes any payment of the Purchased Royalties to the Seller or any of its Subsidiaries, then (i) such amount shall be held by the Seller (or such Subsidiary) in trust for the benefit of the Purchaser, (ii) the Seller (or such Subsidiary) shall have no right, title or interest whatsoever in such payment and shall not create or suffer to exist any Lien thereon and (iii) the Seller (or such Subsidiary) promptly, and in any event no later than five Business Days following the receipt by the Seller (or such Subsidiary) of such payment, shall remit such portion of such payment to the Purchaser Account pursuant to Section 5.4(b) in the exact form received with all necessary endorsements.
- (b) All payments required to be made to the Purchaser pursuant to this Purchase and Sale Agreement shall be made by wire transfer of immediately available funds, without Set-Off or deduction or withholding for or on account of any Taxes (except as required by Applicable Law, but subject to Section 5.10(a)), to the account provided by the Purchaser in writing (or to such other account as the Purchaser shall notify the Seller in writing from time to time) (the "Purchaser Account").
- (c) If, notwithstanding the terms of the Licensee Instruction and the Escrow Agreement, the Licensee, any of its Affiliates, any of its sublicensees or any other Person makes any payment under the Commercialization Agreement to the Purchaser or any Affiliate of the Purchaser that does not consist entirely of Purchased Royalties, then (i) the portion of such payment that does not constitute Purchased Royalties shall be held by the Purchaser or such Affiliate in trust for the benefit of the Seller, (ii) the Purchaser or such Affiliate shall have no right, title or interest whatsoever in such payment and shall not create or suffer to exist any Lien thereon and (iii) the Purchaser promptly, and in any event no later than five Business Days following the receipt by the Purchaser of such payment, shall remit such payment to the Seller Account pursuant to Section 5.4(d).

(d) The Purchaser shall make all payments required to be made by it to the Seller pursuant to this Purchase and Sale Agreement by wire transfer of immediately available funds, without Set-Off to the account provided by the Seller in writing (or to such other account as the Seller shall notify the Purchaser in writing from time to time) (the "Seller Account").

(e) If the Licensee takes any Set-Off against the Purchased Royalties (other than as a result of a Permitted Reduction actually taken or for any prior overpayment of Purchased Royalties actually made to the Purchaser) for any liability, debt or other obligation that the Seller owes or allegedly owes to the Licensee, then the Seller shall cause the amount of such Set-Off to be paid promptly (but in no event later than [[\*\*\*]]Business Days) following such Set-Off to the Purchaser Account. If the Licensee subsequently makes a payment to the Purchaser in respect of a Set-Off previously taken against the Purchased Royalties and the Seller previously made a payment to the Purchaser in the amount of such Set-Off pursuant to the foregoing sentence, then the Purchaser shall promptly (but in no event later than [[\*\*\*]] Business Days) after the Purchaser receives such payment by the Licensee, pay to the Seller the amount of such payment.

# Section 5.5 Commercialization Agreement.

(a) The Seller (i) shall perform and comply in all material respects with its obligations under the Commercialization Agreement and the Manufacturing and Supply Agreement, (ii) shall not, without the prior written consent of the Purchaser, forgive, release or compromise any Purchased Royalties payable under the Commercialization Agreement, and (iii) shall not, except as Mutually Agreed, (A) amend, modify, supplement, restate, waive, cancel or terminate (or consent to any amendment, modification, supplement, restatement, waiver, cancellation or termination of), in whole or in part, any provision of or right under the Commercialization Agreement, except for any amendments of the Commercialization Agreement (1) wherein Licensee agrees to perform any of the Seller's obligations under the Commercialization Agreement (provided that Licensee agrees to the same standard of performance of such obligations as was required of the Seller and such amendment does not forgive, release or compromise any Purchased Royalties payable under the Commercialization Agreement), or (2) regarding the proposed amendments with respect to the Atara 205 Study as set forth on Schedule 3.14, (B) enter into any new contract, agreement or legally binding arrangement in respect of the Purchased Royalties, or (C) enter into any new contract, agreement or legally binding arrangement in respect of the Intellectual Property Rights or the Commercialization Agreement, in each case with respect to the Product in the Field in the Territory. The Seller shall promptly (and in any case within [[\*\*\*]] Business Days and subject to applicable confidentiality obligations) deliver to the Purchaser copies of all fully-executed or definitive writings related to the matters set forth in clause (iii) of the immediately preceding sentence.

(b) Except as otherwise expressly set forth in this <u>ARTICLE V</u> and except as Mutually Agreed, the Seller shall not grant or withhold any consent, exercise or waive any right or option, fail to exercise any right or option in respect of, affecting or relating to (i) the Purchased Royalties, or (ii) the Commercialization Agreement if, in either case, doing so would (A) reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect or (B) cause a termination, material breach or material default under the Commercialization Agreement. The Seller shall promptly (and in any case within five Business Days) deliver to the Purchaser copies of all fully executed or definitive writings related to the matters set forth in the immediately preceding sentence.

(c) Promptly (and in any case within [[\*\*\*]] Business Days) after (i) receiving notice from the Licensee (A) terminating the Commercialization Agreement (in whole or in part), or (B) alleging any breach of or default under the Commercialization Agreement by the Seller related to the Purchased Royalties, or any other material breach or material default under the Commercialization Agreement, or (ii) the Seller gains Knowledge of any facts, circumstances or events that, alone or together with other

facts, circumstances or events, would reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to (A) a breach of or default under the Commercialization Agreement by the Seller related to the Purchased Royalties, or (B) the right to terminate the Commercialization Agreement (in whole or in part) by the Licensee, in each case the Seller shall (1) (x) give written notice thereof to the Purchaser and provide the Purchaser with a written summary of the material details thereof, (y) to the extent not prohibited by obligations of confidentiality contained in the Commercialization Agreement, include a copy of any written notice received from the Licensee, and (z) in the case of any such breach or default or alleged breach or default by the Seller, describe in reasonable detail any corrective action the Seller proposes to take in respect of such breach or default, and (2) in the case of any such breach or default or alleged breach or default by the Seller, use commercially reasonable efforts to cure such breach or default and give written notice to the Purchaser upon curing such breach or default; provided, however, that, if the Seller fails to promptly cure any such breach or default, the Seller shall, as Mutually Agreed, take any reasonable actions the Purchaser and Seller consider reasonably necessary to promptly cure such breach or default.

(d) Promptly (but in any event, within [[\*\*\*]] Business Days) after the Seller obtains Knowledge of any actual or alleged breach of or default that relates to the Purchased Royalties or any other actual or alleged material breach of or material default under the Commercialization Agreement by the Licensee or any sublicensee (each, a "Defaulting Party") or of the existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, would reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to any such breach of or default or the right to terminate the Commercialization Agreement (in whole or in part) by the Seller, in each case the Seller shall give written notice thereof to the Purchaser and provide the Purchaser with a written summary of the material details thereof and [[\*\*\*]] take such permissible actions (including commencing legal action against the Defaulting Party and the selection of legal counsel reasonably satisfactory to the Purchaser) to enforce compliance by the Defaulting Party with the relevant provisions of the applicable Commercialization Agreement and to exercise any or all of the Seller's rights and remedies, whether under such Commercialization Agreement or by operation of law, with respect thereto. The Purchaser shall, except to the extent prohibited by the obligations of confidentiality contained in the Commercialization Agreement, have the right, at its sole cost and expense, to attend (or, if the Seller is required to act as directed by the Purchaser pursuant to this Section 5.5(d), participate in) any meeting, discussion, action, suit or other proceeding relating to any such breach, default or termination event or alleged breach, default or termination event, including any counterclaim, settlement discussions or meetings; provided, however, that the Purchaser shall have no such right to attend or participate, as applicable, if the exercise thereof would adversely affect the maintenance by the Seller of any applicable attorney-client privilege (and, in such event, the Parties agree to use commercially reasonable efforts to effect such other arrangements to preserve such privilege, including negotiating to enter into a mutually-acceptable joint defense agreement).

(e) All proceeds resulting from any enforcement of Licensee's obligations under the Commercialization Agreement shall be applied (i) first, [[\*\*\*]] and (ii) second, [[\*\*\*]]. The remainder of such proceeds that are in respect of an unpaid portion of the Purchased Royalties shall be allocated to [[\*\*\*]].

### (f) Patent Prosecution, Enforcement and Defense.

(i) To the extent required or permitted by the Commercialization Agreement and the MSK Agreement, the Seller shall take any and all actions, and prepare, execute, deliver and file any and all agreements, documents and instruments, that are reasonably necessary or desirable to diligently preserve and maintain the applicable Licensed Patents, including payment of maintenance fees or annuities. In connection with any actions or decisions by the Seller not to

act in respect of matters contemplated by the foregoing sentence, to the extent such action or decision would reasonably be expected to have a Material Adverse Effect, the Seller shall provide advance written notice of all such actions or decisions not to act in order to consult with the Purchaser, and the Seller shall, in good faith, give due consideration to any reasonable suggestions of the Purchaser.

- (ii) To the extent required or permitted by the Commercialization Agreement and the MSK Agreement [[\*\*\*]], the Seller shall (A) diligently defend (and enforce) the Intellectual Property Rights against infringement or interference by any other Person, and against any claims of invalidity or unenforceability, in any jurisdiction in the Territory (including by bringing any legal action for infringement or defending any counterclaim of invalidity or action of any other Person for declaratory judgment of non-infringement or non-interference) and (B) when available in respect of any Licensed Patent, obtain issued patents and any corrections, substitutions, reissues and reexaminations thereof and obtain patent term extensions, supplementary protection certificates and any other forms of patent term extension or restoration in any country in the Territory. In connection with the Seller's actions or decisions not to act in respect of matters contemplated by the foregoing sentence, the Seller shall provide advance written notice of all such material actions or material decisions not to act in order to consult with the Purchaser, if applicable, and, if applicable, allow the Purchaser sufficient time to issue instructions. The Seller shall promptly (but in any event, within [[\*\*\*]] Business Days) provide to the Purchaser a copy of any written notice or other documentation received in connection with any such legal action, suit or other proceeding.
- (iii) The Seller shall, except to the extent prohibited by obligations of confidentiality contained in the Commercialization Agreement or the MSK Agreement, and except for routine prosecution correspondence and documentation, promptly (but in any event, within [[\*\*\*]] Business Days) after receipt thereof, provide to the Purchaser a copy of all substantive written notices or other material documentation relating to the patentability, enforceability, validity, scope or term of the Licensed Patents, and shall provide the Purchaser with a copy of drafts of any written material proposed to be filed in response thereto.
- (iv) All proceeds resulting from any enforcement of Licensed Patents by the Seller against infringement or interference by any other Person, and against any claims of invalidity or unenforceability, in any jurisdiction in the Territory shall be applied (i) first, [[\*\*\*]] and (ii) second, [[\*\*\*]]. The remainder of such proceeds that are in respect of an unpaid portion of the Purchased Royalties shall be allocated to [[\*\*\*]].
- (g) Except in connection with any assignment by the Seller of its rights and a delegation by the Seller of its obligations under this Purchase and Sale Agreement pursuant to and in accordance with Section 10.3, the Seller shall not dispose of, assign or otherwise transfer, in whole or in part, (i) the Commercialization Agreement or the Purchased Royalties, or (ii) any of the Seller's right, title or interest in or to the applicable Intellectual Property Rights in the Field in the Territory. The Seller shall not grant any Lien on the Purchased Royalties.
- (h) The Purchaser and the Seller shall bear the reasonable out-of-pocket costs and expenses (including the reasonable fees and expenses of counsel) in connection with the actions pursuant to this <u>Section 5.5</u> [[\*\*\*]]. The Purchaser shall promptly on demand reimburse the Seller for [[\*\*\*]] of such costs and expenses incurred by the Seller in connection with such actions.

Section 5.6 Termination of the Commercialization Agreement.

- (a) Without limiting the provisions of Section 5.5 or any other rights or remedies the Purchaser may have under this Purchase and Sale Agreement, if Licensee terminates or provides written notice of termination of the Commercialization Agreement or the Commercialization Agreement otherwise terminates (whether in whole or in part in respect of any Product in any country in the Territory), in any case during the Royalty Term for such country, then the Seller shall have the exclusive right, following the effective date of such termination, and shall use commercially reasonable efforts to negotiate a license with a Third Party under the Intellectual Property Rights for such Third Party to make, have made, use, import, offer for sale and sell Products in the Field in applicable terminated country(ies) within the Territory for any purpose that Licensee would have been permitted to make, have made, use, import, offer for sale and sell Products under the Commercialization Agreement (and, if such termination is only in part in respect of a Product in a particular country (and not in whole), such license (x) shall apply only to such country and (y) shall not apply to any product that would have constituted a Product under the Commercialization Agreement other than the Product that was the subject of such termination), which license shall (i) become effective not earlier than the effective date of such termination, (ii) expire not later than the last day of the Royalty Term (and, if such termination is only in part in respect of a Product in a particular country (and not in whole), the Royalty Term shall be such term that is applicable under the Commercialization Agreement for such Product in such country) and (iii) include terms, conditions and limitations that are not materially less favorable to the Seller, taking into account the sale of the Purchased Royalties pursuant to the Transaction Documents, than those contained in the Commercialization Agreement, including with respect to obligations and costs imposed on the Seller, disclaimers of the Seller's liability, intellectual property ownership and control and indemnification of the Seller (any such license, a "New Arrangement"). The Seller shall reasonably consider any comments from the Purchaser with respect to such negotiation of a New Arrangement.
- (b) Should the Seller identify any New Arrangement pursuant to <u>Section 5.6(a)</u>, the Seller agrees to promptly duly execute and deliver a new license agreement effecting such New Arrangement that satisfies the foregoing requirements.
- (c) The Purchaser and the Seller shall bear the reasonable out-of-pocket costs and expenses (including the reasonable fees and expenses of counsel) in connection with the actions pursuant to this <u>Section 5.6</u> [[\*\*\*]]. The Purchaser shall promptly on demand reimburse the Seller for [[\*\*\*]] of such costs and expenses incurred by the Seller in connection with such actions.

#### Section 5.7 MSK Agreement.

- (a) The Seller (i) shall perform and comply in all material respects with its obligations under the MSK Agreement, and (ii) shall not, except as Mutually Agreed, amend, modify, supplement, restate, waive, cancel or terminate (or consent to any amendment, modification, supplement, restatement, waiver, cancellation or termination of), in whole or in part, any provision of or right under the MSK Agreement with respect to the Licensed Patents in the Field in the Territory. The Seller shall promptly (and in any case within [[\*\*\*]] Business Days and subject to applicable confidentiality obligations) deliver to the Purchaser copies of all fully-executed or definitive writings related to the matters set forth in clause (ii) of the immediately preceding sentence.
- (b) Except as otherwise expressly set forth in this <u>ARTICLE V</u> and except as Mutually Agreed, the Seller shall not grant or withhold any consent, exercise or waive any right or option, fail to exercise any right or option in respect of, affecting or relating to the MSK Agreement if, in either case, doing so would (i) reasonably be expected (with or without the giving of notice or passage of time, or both) to have a Material Adverse Effect or (ii) cause a termination, material breach or material default under the MSK Agreement. The Seller shall promptly (and in any case within [[\*\*\*]] Business Days)

deliver to the Purchaser copies of all fully executed or definitive writings related to the matters set forth in the immediately preceding sentence.

- (c) Promptly (and in any case within [[\*\*\*]] Business Days) after (i) receiving notice from MSK (A) terminating the MSK Agreement (in whole or in part), or (B) alleging any material breach or material default under the MSK Agreement, or (ii) the Seller gains Knowledge of any facts, circumstances or events that, alone or together with other facts, circumstances or events, would reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to the right to terminate the MSK Agreement (in whole or in part) by MSK, in each case the Seller shall (1) (x) give written notice thereof to the Purchaser and provide the Purchaser with a written summary of the material details thereof, (y) to the extent not prohibited by obligations of confidentiality contained in the MSK Agreement, include a copy of any written notice received from MSK, and (z) in the case of any such breach or default or alleged breach or default by the Seller, describe in reasonable detail any corrective action the Seller proposes to take in respect of such breach or default, and (2) in the case of any such breach or default or alleged breach or default by the Seller, use commercially reasonable efforts to cure such breach or default and give written notice to the Purchaser upon curing such breach or default; provided, however, that, if the Seller fails to promptly cure any such breach or default, the Seller shall, as Mutually Agreed, take any reasonable actions the Purchaser and Seller consider reasonably necessary to promptly cure such breach or default.
- (d) Promptly (but in any event, within [[\*\*\*]] Business Days) after the Seller obtains Knowledge of any actual or alleged material breach of or material default under the MSK Agreement by MSK or of the existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, would reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to any such breach of or default or the right to terminate the MSK Agreement (in whole or in part) by the Seller, in each case the Seller shall give written notice thereof to the Purchaser and provide the Purchaser with a written summary of the material details thereof and act as Mutually Agreed to take such permissible actions (including commencing legal action against MSK and the selection of legal counsel reasonably satisfactory to the Purchaser) to enforce compliance by MSK with the relevant provisions of the MSK Agreement and to exercise any or all of the Seller's rights and remedies, whether under the MSK Agreement or by operation of law, with respect thereto. The Purchaser shall, except to the extent prohibited by the obligations of confidentiality contained in the MSK Agreement, have the right, at its sole cost and expense, to attend (or, if the Seller is required to act as directed by the Purchaser pursuant to this Section 5.7(d), participate in) any meeting, discussion, action, suit or other proceeding relating to any such breach, default or termination event or alleged breach, default or termination event, including any counterclaim, settlement discussions or meetings; provided, however, that the Purchaser shall have no such right to attend or participate, as applicable, if the exercise thereof would adversely affect the maintenance by the Seller of any applicable attorney-client privilege (and, in such event, the Parties agree to use commercially reasonable efforts to effect such other arrangements to preserve such privilege, including negotiating to enter into a mutually-acceptabl
- (e) All proceeds resulting from any enforcement of MSK's obligations under the MSK Agreement shall be applied (i) first, [[\*\*\*]] and (ii) second, [[\*\*\*]]. The remainder of such proceeds shall be allocated to [[\*\*\*]].

Section 5.8 Audits.

(a) The Seller may, and, if requested in writing by the Purchaser (no more frequently than once per Calendar Year), shall, to the extent permitted by Section 11.10 of the Commercialization Agreement, cause an inspection or audit of the Licensee's books and records to be conducted pursuant to

and in accordance with Section 11.10 of the Commercialization Agreement. The Seller shall retain the exclusive right to inspect and audit the Licensee's books and records at any time and from time to time at its sole discretion. With respect to any inspection or audit requested by the Purchaser, the Seller shall appoint such public accounting firm of nationally recognized standing as the Purchaser shall select for such purpose (it being understood and agreed that any such public accounting firm shall, pursuant to Section 11.10 of the Commercialization Agreement, be reasonably acceptable to Licensee). The Seller and the Purchaser agree that the expenses of any inspection or audit carried out at the request of the Purchaser pursuant to this Section 5.8(a) that would otherwise be borne by the Seller pursuant to the Commercialization Agreement shall instead be borne by the Purchaser and reimbursed to the Seller promptly on demand, including such reasonable fees and expenses of such public accounting firm as are to be borne by the Seller pursuant to Section 11.10 of the Commercialization Agreement, together with the Seller's out-of-pocket costs and expenses incurred in connection with such inspection or audit; provided that the Purchaser shall be reimbursed by the Seller for any such fees and expenses to the extent the Seller is reimbursed by Licensee; provided, further, that, for the avoidance of doubt, any audit caused by the Seller pursuant to the first sentence of this Section 5.8(a) that is not requested by the Purchaser shall not be deemed to be carried out at the request of the Purchaser, and the Purchaser shall have no obligation to reimburse the Seller for any fees, costs or expenses incurred by the Seller in connection therewith. The Seller shall, to the extent not prohibited by obligations of confidentiality contained in the Commercialization Agreement pursuant to which an inspection or audit in respect of the Purchased Royalties is conducted, promptly (but in no event later than [[\*\*\*]] Business Days) fu

(b) In the event that any inspection or audit conducted pursuant to Section 5.8(a) uncovers that the amounts actually paid to the Purchaser for any period in respect of the Purchased Royalties were greater than the amounts that should have been paid to the Purchaser for such period in respect of the Purchased Royalties, the Purchaser shall cause the amount of such overpayment to be paid to the Licensee promptly (but in no event later than [[\*\*\*]] Business Days) after delivery to the Purchaser, pursuant to Section 5.8(a), of the applicable inspection or audit report or certificate, as the case may be, showing such overpayment. In the event that any inspection or audit conducted pursuant to Section 5.8(a) uncovers that the amounts actually paid to the Purchaser for any period in respect of the Purchased Royalties were less than the amounts that should have been paid to the Purchaser for such period in respect of the Purchased Royalties, the Seller shall cooperate and provide assistance as reasonably requested by the Purchaser to cause the amount of such underpayment to be paid to the Purchaser by the Licensee in accordance with the timeframe set forth in the applicable Commercialization Agreement promptly after delivery to the Purchaser, pursuant to Section 5.8(a), of the applicable inspection or audit report or certificate, as the case may be, showing such underpayment.

Section 5.9 <u>Protective Covenants</u>. During the Term, the Seller shall not, and shall not permit any Subsidiary to, without the prior written consent of Purchaser:

(a) forgive, release or compromise any amount owed to Seller or its Subsidiaries or its Affiliates that would constitute Purchased Royalties; or

(b) directly or indirectly create, incur, assume or permit to exist any Lien on or with respect to any the Purchased Royalties, or file or permit the filing of, or permit to remain in effect, any financing statement or other similar notice of any Lien with respect to the Purchased Royalties, except Permitted Liens.

Section 5.10 <u>Tax Matters</u>.

- (a) The Seller shall notify the Purchaser in writing promptly (but in no event later than [[\*\*\*]] Business Days) following the receipt of any written notification by the Licensee or by an Affiliate of the Licensee that it intends to make any Permitted Tax Withholding; provided that Seller has no obligation to notify Purchaser of any Permitted Tax Withholding due to Purchaser's failure to provide any Purchaser Tax Forms at least ten Business Days prior to the due date of the applicable payment of the Purchased Royalties by the Licensee. The Seller shall, upon the reasonable request of the Purchaser and at the Purchaser's expense, reasonably cooperate with the Purchaser and use its commercially reasonable efforts to make such filings and take such other actions as may be reasonably necessary and specified by the Purchaser in order to allow an exemption from or reduction of any Permitted Tax Withholding; provided that Seller shall have no obligation under this sentence in respect of any withholding Tax resulting from Purchaser's failure to provide any Purchaser Tax Forms at least ten Business Days prior to the due date of the applicable payment of the Purchased Royalties by the Licensee.
- (b) As promptly as practicable after the Closing Date (and from time to time thereafter upon the reasonable request of the Seller or the Licensee), the Purchaser shall deliver properly executed and duly completed versions of the applicable French tax forms number 5000 and 5003, as such forms may be amended from time to time, or such other appropriate documentation evidencing the Purchaser's exemption from French withholding tax on royalty payments (as mutually agreed by the Parties) (collectively, the "Purchaser Tax Forms"). Any amounts payable to Purchaser under this Agreement shall be net of any applicable withholding Taxes, including, for the avoidance of doubt, any applicable withholding Taxes due to a failure of the Purchaser to timely provide any Purchaser Tax Forms (and any amounts so withheld shall be treated as having been paid to Purchaser). If, as a result of any failure by Purchaser to provide any Purchaser Tax Forms within the time frame set forth in Section 5.10(a), except for any such failure resulting from a change in law after the date on which the Purchaser provides its initial Purchaser Tax Forms, (i) the amount of funds that would have been distributed to Seller from the Escrow Account had Purchaser timely provided the Purchaser Tax Forms is greater than (ii) the amount of funds in the Escrow Account to be distributed to Seller (such excess, the "Shortfall"), Purchaser shall indemnify and hold harmless Seller for the Shortfall and any other Losses incurred by Seller as a result of Purchaser's failure to timely provide the Purchaser Tax Forms.

Section 5.11 Escrow Agreement. The Parties agree to negotiate and enter into an Escrow Agreement within 60 days of the Closing Date.

## ARTICLE VI THE CLOSING

Section 6.1 <u>Closing</u>. The closing of the transactions contemplated hereby (the "<u>Closing</u>") shall take place at 9:00 a.m., Pacific Time, on the date the Purchase Price payment is required to be made pursuant to <u>Section 2.2</u> (or such earlier date as Purchaser may elect in its sole discretion), subject to the satisfaction or waiver of the conditions set forth in <u>Section 6.2</u>, <u>Section 6.3</u>, <u>Section 6.4</u> and <u>Section 6.5</u> being satisfied (the "<u>Closing Date</u>") at the offices of Gibson, Dunn & Crutcher, LLP, 555 Mission Street, Suite 3000, San Francisco, California 94105, or on such other date, at such other time or at such other place, in each case as the Parties mutually agree.

Section 6.2 <u>Conditions to Purchaser's Obligations</u>. The Purchaser's obligation to pay the Purchase Price on the Closing Date, is subject to the satisfaction or waiver, at or prior to the Closing Date, as applicable, of each of the following conditions precedent:

(a) The Seller shall have performed and complied in all material respects with all agreements, covenants, obligations and conditions required to be performed and complied with by it under this Purchase and Sale Agreement at or prior to the Closing Date. The Purchaser shall have

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received a certificate executed by	z an authorized	officer of the	<ul> <li>Seller on the</li> </ul>	( losing I late	certitying on	hehalf of the	Seller to the	ettect at th	ie foregoing

- (b) The representations and warranties of the Seller contained in <u>ARTICLE III</u> shall be true and correct in all material respects as of the Closing Date, except to the extent any such representation or warranty expressly speaks as of a particular date, in which case it shall be true and correct in all material respects as of such date; provided that, to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect," such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the Closing Date or such other date, as applicable. The Purchaser shall have received a certificate executed by an authorized officer of the Seller on the Closing Date certifying on behalf of the Seller to the effect of the foregoing.
- (c) No event or events shall have occurred that, individually or in the aggregate, have had or would reasonably be likely to result in (or, with the giving of notice, the passage of time or otherwise, would result in) a Material Adverse Effect. The Purchaser shall have received a certificate executed by a duly authorized officer of the Seller on the Closing Date certifying on behalf of the Seller to the effect of the foregoing.
- (d) There shall not have been issued and be in effect any judgment, order, writ, injunction, citation, award or decree of any nature of any Governmental Authority enjoining, preventing or restricting the consummation of the transactions contemplated by this Purchase and Sale Agreement.
- (e) There shall not have been instituted or be pending any action or proceeding by any Governmental Authority or any other Person (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (ii) seeking to obtain material damages in connection with the transaction contemplated hereby or (iii) seeking to restrain or prohibit the Purchaser's purchase of the Purchased Royalties.
- Section 6.3 <u>Conditions to Seller's Obligations</u>. The obligations of the Seller to consummate the transactions contemplated hereunder are subject to the satisfaction or waiver, at or prior to the Effective Date and on the Closing Date, as applicable, of each of the following conditions precedent:
- (a) The Purchaser shall have performed and complied in all material respects with all agreements, covenants, obligations and conditions required to be performed and complied with by it under this Purchase and Sale Agreement at or prior to the Closing Date. The Seller shall have received a certificate executed by an authorized officer of the Purchaser on the Closing Date certifying on behalf of the Purchaser to the effect of the foregoing.
- (b) The representations and warranties of the Purchaser contained in <u>ARTICLE IV</u> shall have been true and correct in all material respects as of the Closing Date, respectively, except to the extent any such representation or warranty expressly speaks as of a particular date, in which case it shall be true and correct in all material respects as of such date; provided, that to the extent that any such representation or warranty is qualified by the term "material," or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the Closing Date or such other date, as applicable. The Seller shall have received a certificate executed by an authorized officer of the Purchaser on the Closing Date certifying on behalf of the Purchaser to the effect of the foregoing.

- (c) There shall not have been issued and be in effect any judgment, order, writ, injunction, citation, award or decree of any Governmental Authority enjoining, preventing or restricting the consummation of the transactions contemplated by this Purchase and Sale Agreement.
- (d) There shall not have been instituted or be pending any action or proceeding by any Governmental Authority or any other Person (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (ii) seeking to obtain material damages in connection with the transactions contemplated hereby or (iii) seeking to restrain or prohibit the Purchaser's purchase of the Purchased Royalties.

Section 6.4 <u>Closing Deliverables of the Seller</u>. At the Closing, Seller shall deliver or cause to be delivered to the Purchaser the following:

- (a) the Bill of Sale duly executed by the Seller;
- (b) the Licensee Instruction duly executed by the Seller;
- (c) a valid, true and properly executed IRS Form W-9 (or any applicable successor form) certifying that the Seller is a "United States Person" and is exempt from United States federal backup withholding tax with respect to any and all payments made to the Seller hereunder;
- (d) a certificate of an executive officer of the Seller dated as of the Closing Date (i) attaching copies, certified by such officer as true and complete, of (x) the organizational documents of the Seller and (y) resolutions of the governing body of the Seller authorizing and approving the execution, delivery and performance by the Seller of the Transaction Documents and the transactions contemplated hereby and thereby, (ii) setting forth the incumbency of the officer or officers of the Seller who have executed and delivered the Transaction Documents, including therein a signature specimen of each such officer or officers and (iii) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Seller's jurisdiction of organization, stating that the Seller is in good standing under the laws of such jurisdiction; and
- (e) A confirmation that the Seller has scheduled delivery to the Purchaser of an electronic copy of all documents uploaded as of the Closing Date to the electronic data room maintained by the Seller related to the transactions contemplated by this Purchase and Sale Agreement.
- Section 6.5 <u>Closing Deliverables of the Purchaser</u>. At the Closing, the Purchaser shall deliver or cause to be delivered to the Seller the following:
  - (a) the Bill of Sale duly executed by the Purchaser;
- (b) a valid, true and properly executed IRS Form W-9 (or any applicable successor form) for the Purchaser certifying that the Purchaser is a "United States Person" and is exempt from United States federal backup withholding tax with respect to any and all payments made to the Purchaser in respect of the Purchased Royalties;
  - (c) the Purchase Price in accordance with Section 2.2; and
- (d) a certificate of an executive officer of the Purchaser dated as of the Closing Date and setting forth the incumbency of the officer or officers of the Purchaser who have executed and

delivered the Transaction Documents to which the Purchaser is a party, including therein a signature specimen of each such officer or officers.

# ARTICLE VII INDEMNIFICATION

Section 7.1 Indemnification by the Seller. The Seller agrees to indemnify and hold harmless each of the Purchaser and its Affiliates and any or all of their respective partners, directors, trustees, officers, managers, employees, members, agents and controlling persons (each, a "Purchaser" Indemnified Party") from and against, and will pay to the Purchaser Indemnified Party the amount of, any and all Losses awarded against or incurred or suffered by the Purchaser Indemnified Party, whether or not involving a Third-Party Claim, arising out of (a) any breach of any representation or warranty made by the Seller in any of the Transaction Documents or in any certificate delivered by the Seller to the Purchaser in writing pursuant to this Purchase and Sale Agreement, (b) any breach of or default under any covenant or agreement of the Seller in any of the Transaction Documents, (c) any Excluded Liabilities and Obligations or (d) any brokerage or finder's fees or commissions or similar amounts incurred or owed by the Seller to any brokers, financial advisors or comparable other Persons retained or employed by it in connection with the transactions contemplated by this Purchase and Sale Agreement; provided, however, that the foregoing shall exclude any indemnification to any Purchaser Indemnified Party (i) that has the effect of imposing on the Seller any liability to make payments of or in lieu of the Purchased Royalties because of any Credit Event or the insufficiency of the Purchased Royalties, whether as a result of the amount of cash flow arising from sales or licensing of the Product or otherwise, in any case unless directly resulting from the breach or default by the Seller of or under any of the Transaction Documents, (ii) for any matter in respect of which any Seller Indemnified Party would be entitled to indemnification under Section 7.2, (iii) to the extent resulting from the fraud, bad faith, gross negligence, or willful misconduct of any Purchaser Indemnified Party, (iv) to the extent resulting from the failure of the Licensee to perform any of its obligations under the Commercialization Agreement, unless directly resulting from the breach or default by the Seller of or under the Commercialization Agreement, or (v) to the extent resulting from acts or omissions of the Seller based upon the written instructions from any Purchaser Indemnified Party. Any undisputed amounts due to any Purchaser Indemnified Party hereunder shall be payable by the Seller to the Purchaser Indemnified Party upon demand.

Section 7.2 <u>Indemnification by the Purchaser</u>. The Purchaser agrees to indemnify and hold harmless each of the Seller and its Affiliates and any or all of their respective partners, directors, trustees, officers, managers, members, employees, agents and controlling persons (each, a "<u>Seller Indemnified Party</u>") from and against, and will pay to each Seller Indemnified Party the amount of, any and all Losses awarded against or incurred or suffered by such Seller Indemnified Party, whether or not involving a Third-Party Claim, arising out of (a) any breach of any representation or warranty made by the Purchaser in any of the Transaction Documents or in any certificate delivered by the Purchaser to the Seller in writing pursuant to this Purchase and Sale Agreement, (b) any breach of or default under any covenant or agreement of the Purchaser in any Transaction Document to which the Purchaser is party or in the Existing Confidentiality Agreement or (c) any brokerage or finder's fees or commissions or similar amounts incurred or owed by the Purchaser to any brokers, financial advisors or comparable other Persons retained or employed by it in connection with the transactions contemplated by this Purchase and Sale Agreement; <u>provided, however</u>, that the foregoing shall exclude any indemnification to any Seller Indemnified Party (i) to the extent resulting from the fraud, bad faith, gross negligence, or willful misconduct of any Seller Indemnified Party, (ii) for any matter in respect of which any Purchaser Indemnified Party would be entitled to indemnification under <u>Section 7.1</u> or (iii) to the extent resulting from acts or omissions of the Purchaser based upon the written instructions from any Seller Indemnified Party upon demand.

## Section 7.3 Procedures for Third-Party Claims.

- (a) If any Third-Party Claim shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to Section 7.1 or Section 7.2, the indemnified party shall, promptly after receipt of notice of the commencement of such Third-Party Claim, notify the indemnifying party in writing of the commencement thereof, enclosing a copy of all papers served, if any; provided that the omission to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under Section 7.1 or Section 7.2 unless, and only to the extent that, the indemnifying party is actually prejudiced by such omission.
- (b) In the event that any Third-Party Claim is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof in accordance with this Section 7.3, the indemnifying party will be entitled, at the indemnifying party's sole cost and expense, to participate therein and, to the extent that it may wish, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party (who shall not, except with the consent of the indemnifying party, be counsel to the indemnified party), and, after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, subject to clause (c), the indemnifying party will not be liable to such indemnified party under this ARTICLE VII for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof.
- (c) In any such Third-Party Claim, an indemnified party shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the sole cost and expense of such indemnified party unless (a) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (b) the indemnifying party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or (c) the named parties to any such Third-Party Claim (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them based on the advice of counsel to the indemnified party. It is agreed that the indemnifying party shall not, in connection with any Third-Party Claim or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate law firm (in addition to local counsel where necessary) for all such indemnified parties.
- (d) The indemnifying party shall not be liable for any settlement of any Third-Party Claim effected without its written consent, but, if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any Loss by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or discharge of any pending or threatened Third-Party Claim in respect of which any indemnified party is or could have been a party and indemnity could be sought hereunder by such indemnified party, unless such settlement, compromise or discharge, as the case may be, (i) includes an unconditional, full written release of such indemnified party, in form and substance reasonably satisfactory to the indemnified party, from all liability on claims that are the subject matter of such claim or proceeding, (ii) does not include any statement as to an admission of fault, culpability or failure to act by or on behalf of any indemnified party and (iii) does not impose any continuing obligations or restrictions other than customary and reasonable confidentiality obligations relating to such claim, settlement or compromise.

Section 7.4 Other Claims. A claim by an indemnified party under this ARTICLE VII for any matter not involving a Third-Party Claim and in respect of which such indemnified party would be entitled to indemnification hereunder may be made by delivering, in good faith, a written notice of

demand to the indemnifying party, which notice shall contain (a) a description and the amount of any Losses incurred or suffered or reasonably expected to be incurred or suffered by the indemnified party, (b) a statement that the indemnified party is entitled to indemnification under this <u>ARTICLE VII</u> for such Losses and a reasonable explanation of the basis therefor, and (c) a demand for payment in the amount of such Losses; <u>provided</u>, that the failure to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under <u>Section 7.1</u> or <u>Section 7.2</u> unless, and only to the extent that, the indemnifying party is actually prejudiced by such failure. For all purposes of this <u>Section 7.4</u>, the Seller shall be entitled to deliver such notice of demand to the Purchaser on behalf of the Seller Indemnified Parties, and the Purchaser shall be entitled to deliver such notice of demand to the Seller on behalf of the Purchaser Indemnified Parties.

### Section 7.5 Time Limitations.

(a) The Seller shall have liability under Section 7.1 with respect to any breach of any representation or warranty made by the Seller in any of the Transaction Documents or certificates delivered by the Seller to the Purchaser in writing pursuant to this Purchase and Sale Agreement only if, on or prior to the date that is [[\*\*\*]] after the Closing date (other than (i) Section 3.1 (Organization), Section 3.2 (Authorization), Section 3.7 (No Brokers' Fees), Section 3.11 (UCC Matters) (such representations and warranties, the "Fundamental Representations"), as to which a claim may be made on or prior to the date that is six months after the termination of this Purchase and Sale agreement, and (ii) Section 3.3 (No Conflicts), Section 3.4 (Ownership), Section 3.5 (Governmental and Third Party Authorizations), Section 3.9(a) (Intellectual Property Matters), Section 3.9(d) (Intellectual Property Matters), Section 3.10(a) (Counterparty Agreements), Section 3.10(b) (Counterparty Agreements), Section 3.10(c) (Counterparty Agreements) (solely with respect to the first sentence thereof), Section 3.10(e) (Counterparty Agreements) (solely with respect to the second, third, and sixth sentences thereof), and Section 3.16 (Tax Matters), as to which a claim may be made on or prior to the date that is [[\*\*\*]] after the Closing Date), the Purchaser notifies the Seller of a claim, specifying the factual basis of such claim in reasonable detail.

(b) The Purchaser shall have liability under Section 7.2 with respect to any breach of any representation or warranty made by the Purchaser in any of the Transaction Documents or any certificate delivered by the Purchaser to the Seller in writing pursuant to this Purchase and Sale Agreement only if, on or prior to the date that is [[\*\*\*]] after the Closing Date (other than Section 4.1 (Organization), Section 4.2 (Authorization), Section 4.3 (No Conflicts), as to which a claim may be made on or prior to the date that is [[\*\*\*]] after the termination of this Purchase and Sale Agreement), the Seller notifies the Purchaser of a claim, specifying the factual basis of such claim in reasonable detail.

Section 7.6 Exclusive Remedy. Except in the case of fraud or intentional misrepresentation, and except as set forth in Section 10.1, the indemnification afforded by this ARTICLE VII shall be the sole and exclusive remedy for any and all Losses awarded against or incurred or suffered by a Party in connection with the transactions contemplated by the Transaction Documents, including with respect to any breach of any representation or warranty made by a Party in any of the Transaction Documents or any certificate delivered by a Party to the other Party in writing pursuant to this Purchase and Sale Agreement or any breach of or default under any covenant or agreement by a Party pursuant to any Transaction Document.

Section 7.7 <u>Limitations</u>. Notwithstanding anything in this Purchase and Sale Agreement to the contrary, (a) in no event shall any Party have any liability for special, punitive, exemplary, indirect, incidental, or consequential (including lost profits) damages, whether in contract or tort, regardless of whether the other Party shall be advised, shall have reason to know, or in fact shall know of the possibility of such damages suffered or incurred by any such Seller Indemnified Party or Purchaser

Indemnified Party in connection with this Purchase and Sale Agreement, any of the other Transaction Documents, or any of the transactions contemplated hereby or thereby, except to the extent any such damages are actually paid to a Third Party in accordance with Section 8.3 and (b) the Seller shall not have any liability (i) under Section 7.1(a) (other than with respect to the Fundamental Representations) in excess of an amount [[\*\*\*]], (ii) under Section 7.1 in excess of an amount equal to [[\*\*\*]], and (iii) under Section 7.1 unless and until the aggregate amount of all Losses incurred by the Purchaser Indemnified Party equals or exceeds [[\*\*\*]], in which event the Seller shall be liable for Losses including such amount. Notwithstanding the foregoing, the limitations set forth in this Section 7.7 shall not apply to any claim for indemnification hereunder in the case of fraud, intentional misrepresentation, or willful misconduct. The Parties acknowledge and agree that (a) the Purchaser's Losses, if any, for any indemnifiable events under this Purchase and Sale Agreement will typically include Losses for Purchased Royalties that the Purchaser was entitled to receive in respect of its ownership of the Purchased Royalties but did not receive timely or at all due to such indemnifiable event and (b) subject to this Section 7.7, the Purchaser shall be entitled to make indemnification claims for all such missing or delayed Purchased Royalties that the Purchaser was entitled to receive in respect of its ownership of the Purchased Royalties as Losses hereunder (which claims shall be reviewed and assessed by the Parties in accordance with the procedures set forth in this ARTICLE VII), and such missing or delayed Purchased Royalties shall not be deemed special, punitive, exemplary, indirect, incidental, consequential, or lost profits for any purpose of this Purchase and Sale Agreement. For the avoidance of doubt, the Seller shall have no liability to the Purchaser or any Purchaser Indemnified Party for any Permitted Reduct

## ARTICLE VIII CONFIDENTIALITY

Section 8.1 <u>Confidentiality</u>. Except as provided in this <u>ARTICLE VIII</u> or otherwise agreed in writing by the Parties, the Parties agree that, during the term of this Purchase and Sale Agreement and until the [[\*\*\*]] anniversary of the date of termination of this Purchase and Sale Agreement, each Party (the "<u>Receiving Party</u>") shall keep confidential, and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Purchase and Sale Agreement (which includes the exercise of any rights or the performance of any obligations hereunder), any information (whether written or oral, or in electronic or other form) furnished to it by or on behalf of the other Party (the "<u>Disclosing Party</u>") pursuant to the Existing Confidentiality Agreement or this Purchase and Sale Agreement, including the terms of this Purchase and Sale Agreement (such information, "<u>Confidential Information</u>" of the Disclosing Party), except for that portion of such information that:

- (a) was already in the Receiving Party's possession on a non-confidential basis prior to its disclosure to it by the Disclosing Party, or becomes known to the Receiving Party from a source other than the Disclosing Party and its representatives without any breach of this Purchase and Sale Agreement, in each case as evidenced by written records (<u>provided</u>, if such information was disclosed to the Receiving Party on a non-confidential basis by a source that is not the Disclosing Party, such source to the knowledge of the Receiving Party had the right to disclose such information to the Receiving Party without any legal, contractual or fiduciary obligation to any person with respect to such information);
- (b) is or becomes generally available to the public other than as a result of an act or omission by the Receiving Party or its Affiliates in breach of this Purchase and Sale Agreement; or
- (c) was independently developed by the Receiving Party, as evidenced by written records, without use of or reference to the Confidential Information or in violation of the terms of this Purchase and Sale Agreement.

Section 8.2 <u>Termination of Confidentiality Agreement</u>. Effective upon the date hereof, the Existing Confidentiality Agreement shall terminate and be of no further force or effect, and shall be superseded by the provisions of this <u>ARTICLE VIII</u>.

Section 8.3 Required Disclosure. In the event that the Receiving Party or its Affiliates or any of its or its Affiliates' representatives are requested by a Governmental or Regulatory Authority or required by Applicable Law, regulation or legal process (including the regulations of a stock exchange or governmental or regulatory authority or the order or ruling of a court, administrative agency or other government or regulatory body of competent jurisdiction) to disclose any Confidential Information, the Receiving Party shall promptly, to the extent permitted by Applicable Law, notify the Disclosing Party in writing of such request or requirement so that the Disclosing Party may seek an appropriate protective order or other appropriate remedy (and if the Disclosing Party seeks such an order or other remedy, the Receiving Party will provide such cooperation, at the Receiving Party's sole expense, as the Disclosing Party shall reasonably request). If no such protective order or other remedy is obtained and the Receiving Party or its Affiliates or its or its Affiliates' representatives are, in the view of their respective counsel (which may include their respective internal counsel), legally required to disclose Confidential Information, the Receiving Party or its Affiliates or its or its Affiliates' representatives, as the case may be, shall only disclose that portion of the Confidential Information that their respective counsel advises that the Receiving Party or its Affiliates or its Affiliates' representatives, as the case may be, are required to disclose and will exercise commercially reasonable efforts, at the Disclosing Party's sole expense, to obtain reliable assurance that confidential treatment will be accorded to that portion of the Confidential Information that is being disclosed. In any event, the Receiving Party will not oppose action by the Disclosing Party to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded the Confidential Information. Notwithstanding the foregoing, notice to the Disclosing Party shall not be required where disclosure is made (i) in response to a request by a Governmental or Regulatory Authority having competent jurisdiction over the Receiving Party, its Affiliates or its or its Affiliates' representatives, as the case may be, or (ii) in connection with a routine examination by a regulatory examiner, where in each case such request or examination does not expressly reference the Disclosing Party, its Affiliates, the Purchased Royalties or this Purchase and Sale Agreement.

Section 8.4 <u>Permitted Disclosure</u>. The Receiving Party may disclose Confidential Information to the extent such disclosure is reasonably necessary to its Affiliates, its and their employees, directors, officers, contractors, agents, and representatives, and to potential or actual acquirers, merger partners, permitted assignees, (sub)licensees, licensors, investment bankers, investors, limited partners, partners, lenders, or other financing sources (including, in the case of the Seller, any party evaluating the acquisition of any portion of the Royalties that are not included in the Purchased Royalties), and their respective directors, employees, contractors and agents, <u>provided</u> that each such person or entity agrees to confidentiality and non-use obligations with respect thereto at least as stringent as those specified for in this <u>ARTICLE VIII</u>. Further, notwithstanding anything contained in this Agreement, including <u>ARTICLE VIII</u>, to the contrary, the Seller may disclose Confidential Information to the extent such disclosure is reasonably necessary to comply with the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or with any rule, regulation or legal process promulgated by the SEC or a stock exchange, subject to the Seller's obligations set forth in Section 5.2.

Section 8.5 <u>Other Relevant Obligations</u>. In addition to, and without limiting, the Purchaser's obligations under this <u>ARTICLE VIII</u>, the Purchaser shall fully comply with any confidentiality obligations of the Seller or any of its Affiliates under the Commercialization Agreement that are applicable to the Confidential Information.

## ARTICLE IX TERMINATION

Section 9.1 <u>Termination of Agreement</u>. This Purchase and Sale Agreement shall terminate on the earlier of (a) the Royalty Termination Date and (b) the mutual written agreement of the Purchaser and the Seller, except with respect to any rights that shall have accrued prior to such termination, and the Liens and security interests granted to the Purchaser pursuant to this Agreement shall be automatically released without any further action necessary. In furtherance of the foregoing, the Purchaser shall promptly upon Seller's request file UCC-3 terminations and deliver to Seller a lien release letter, in each case, releasing such Liens and security interests, and execute and deliver to the Seller all other documents that the Seller shall reasonably request to evidence such release. If Purchaser has not received notice in accordance with <u>Section 5.1(f)</u> of centralized Marketing Authorization in the European Union of the Product for the treatment of EBV+ PTLD by the European Commission by 5:00 p.m. (Eastern Time) on December 31, 2022, then this Purchase and Sale Agreement shall thereafter terminate at Purchaser's election immediately upon delivery of written notice to the Seller.

Section 9.2 <u>Effect of Termination</u>. Upon the termination of this Purchase and Sale Agreement pursuant to <u>Section 9.1</u>, this Purchase and Sale Agreement shall become void and of no further force and effect; <u>provided, however</u>, that (a) the provisions of <u>ARTICLE I, Section 5.2, Section 5.4(c)</u>, <u>Section 5.4(d)</u>, <u>ARTICLE VIII</u> (solely for the time period specified therein), <u>ARTICLE VIII</u> (solely for the time period specified therein), this <u>Section 9.2</u>, and <u>ARTICLE X</u> (other than <u>Section 10.6</u>) shall survive such termination and shall remain in full force and effect, (b) if, upon the termination of this Purchase and Sale Agreement, any Purchased Royalties or other amounts are payable to the Purchaser, this Purchase and Sale Agreement shall remain in full force and effect until any and all such payments have been made in full, and (except as provided in this <u>Section 9.2</u>) solely for that purpose, and (c) nothing contained in this <u>Section 9.2</u> shall relieve any Party from liability for any breach of this Purchase and Sale Agreement that occurs prior to termination.

# ARTICLE X MISCELLANEOUS

Section 10.1 Specific Performance. Each Party acknowledges and agrees that, if it fails to perform any of its obligations under any of the Transaction Documents, the other Parties will have no adequate remedy at law. In such event, each Party agrees that, without posting bond or other undertaking, the other Parties shall have the right, in addition to any other rights it may have (whether at law or in equity), to seek specific performance of this Purchase and Sale Agreement. Each of the Parties further agrees that, in the event of any action for specific performance, it shall not assert the defense that a remedy at law would be adequate.

Section 10.2 <u>Notices</u>. All notices, consents, waivers and other communications hereunder shall be in writing and shall be effective (a) upon receipt when sent by registered or certified mail, return receipt requested, postage prepaid, with such receipt to be effective the date of delivery indicated on the return receipt, (b) upon receipt when sent by an overnight courier (costs prepaid and receipt requested), (c) on the date personally delivered to an authorized officer of the Party to which sent or (d) upon receipt when sent by e-mail with a confirmation of receipt, addressed to the recipient as follows:

if to the Seller, to:

Atara Biotherapeutics, Inc. 2380 Conejo Spectrum St., Suite 200 Thousand Oaks, CA 91320 USA Attn: Legal Department

with a copy to (which shall not constitute notice):

Gibson, Dunn & Crutcher LLP 555 Mission Street, Suite 3000 San Francisco, CA 94105 USA Attn: Ryan A. Murr & Todd Trattner

Email: rmurr@gibsondunn.com; ttrattner@gibsondunn.com

if to the Purchaser, to:

c/o HealthCare Royalty Partners 300 Atlantic Street, Suite 600 Stamford, CT 06901 Attention: Clarke Futch Tel: 203-487-8301

Email: Clarke.Futch@hcroyalty.com

with a copy to (which shall not constitute notice):

c/o HealthCare Royalty Partners 300 Atlantic Street, Suite 600 Stamford, CT 06901 Attention: Tim Bryant Tel: 312-933-3412

Email: Tim.Bryant@hcroyalty.com

and a copy to (which shall not constitute notice):

Cooley LLP 3 Embarcadero Center 20th Floor San Francisco, CA 94111-4004 Attention: Jason Savich Tel: 415-693-2053 Email: jsavich@cooley.com

Each Party may, by notice given in accordance herewith to the other Party, designate any further or different address to which subsequent notices, consents, waivers and other communications shall be sent.

Section 10.3 Successors and Assigns. The provisions of this Purchase and Sale Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

## Section 10.4 Assignment.

(a) The Seller shall not be entitled to assign any of its rights or delegate any of its obligations under this Purchase and Sale Agreement without the prior written consent of the Purchaser, except that the Seller may, without the consent of the Purchaser, assign its rights and delegate its

obligations under this Purchase and Sale Agreement in its entirety to an Affiliate, Licensee, or any other Third Party that acquires all or substantially all of the Seller's business to which this Purchase and Sale Agreement relates, whether by merger, sale of assets or otherwise; provided, however, that (i) any such assignment to such other Third Party (other than Licensee) will only be permitted to the extent the Commercialization Agreement, the Intellectual Property Rights related to such Commercialization Agreement and the rights and obligations of the Seller hereunder related thereto are transferred together to such Person; and (ii) the assignee under such assignment agrees to be bound by the terms of the Transaction Documents and furnishes a written agreement to the Purchaser to that effect.

(b) Following the Seller's receipt of the Purchase Price, the Purchaser may, without the consent of the Seller, assign any of its rights and delegate any of its obligations under this Purchase and Sale Agreement; provided, however, that, notwithstanding anything to the contrary set forth in this Purchase and Sale Agreement, (i) the Purchaser shall not, without the prior written consent of the Seller, assign any of the Purchased Royalties or any of its rights or delegate any of its obligations (A) to any Competitor or (B) if any such assignment or delegation would otherwise be inconsistent with or violate any of the provisions contained in the Commercialization Agreement or the MSK Agreement, (ii) the Purchaser promptly notifies the Seller of such assignment, (iii) each such assignee complies with Section 6.5(b) (replacing "Purchaser" wherever it appears with such assignee and replacing "Closing" with the date of such assignment), (iv) prior to such assignment, the Purchaser causes such assignee to deliver a writing to the Seller in which such assignee assumes all of the obligations of the Purchaser to the Seller under the Transaction Documents, and (v) if the Purchaser assigns its right under this Agreement to more than one party, the Licensee shall not be required to pay the Royalty to more than one bank account. Notwithstanding the foregoing and anything to the contrary herein, Purchaser may, without the consent of Seller, assign its rights and delegate its obligations under this Purchase and Sale Agreement in its entirety to any Third Party that acquires all or substantially all of the Purchaser's business to which this Purchase and Sale Agreement relates, whether by merger, sale of assets or otherwise; provided, however, that any such assignment to such Third Party will only be permitted to the extent that the assignee under such assignment (1) agrees to be bound by the terms of the Transaction Documents and furnishes a written agreement to that effect, and (2) complies with Section 6.5(b) (replacing "Purch

(c) Each Party shall give written notice to the other Parties of any assignment permitted by this Section 10.4 promptly (but in any event, within five Business Days) after the occurrence thereof. The Seller shall be under no obligation to reaffirm any representations, warranties or covenants made in this Purchase and Sale Agreement or any of the other Transaction Documents or take any other action in connection with any such assignment by any Purchaser or by the Purchaser. Any purported assignment of rights or delegation of obligations in violation of this Section 10.4 will be void.

Section 10.5 <u>Independent Nature of Relationship</u>. The relationship between the Seller and the Purchaser is solely that of seller and purchaser, and neither the Seller nor the Purchaser has any fiduciary or other special relationship with the other Party or any of its Affiliates. This Purchase and Sale Agreement is not a partnership or similar agreement, and nothing contained herein or in any other Transaction Document shall be deemed to constitute the Seller and the Purchaser as a partnership, an association, a joint venture or any other kind of entity or legal form for any purposes, including any Tax purposes. The Parties agree that they shall not take any inconsistent position with respect to such treatment in a filing with any Governmental Authority.

Section 10.6 Expenses. Upon the Closing, the Seller shall reimburse the Purchaser for all Transaction Expenses within 30 days following the Seller's receipt of a detailed invoice from the Purchaser itemizing the Transaction Expenses. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation,

negotiation, execution and delivery of this Purchase and Sale Agreement and to consummate the transactions contemplated hereby shall be paid by the party hereto incurring such fees, costs and expenses.

Section 10.7 Entire Agreement. This Purchase and Sale Agreement, together with the Exhibits and Schedules hereto and the other Transaction Documents, constitute a complete and exclusive statement of the terms of agreement between the Parties, and supersede all prior agreements, understandings and negotiations, both written and oral, between the Parties, with respect to the subject matter of this Purchase and Sale Agreement.

### Section 10.8 Governing Law.

- (a) THIS PURCHASE AND SALE AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE LAWS OF THE STATE OF NEW YORK WITHOUT REFERENCE TO THE RULES THEREOF RELATING TO CONFLICTS OF LAW OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER SHALL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS.
- (b) Each Party irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of (i) the United States District Court for the Southern District of New York and (ii) the Supreme Court of the State of New York, Borough of Manhattan, for purposes of any claim, action, suit or proceeding arising out of this Purchase and Sale Agreement, any of the other Transaction Documents or any of the transactions contemplated hereby or thereby, and agrees that all claims in respect thereof shall be heard and determined only in such courts. Each Party agrees to commence any such claim, action, suit or proceeding only in the United States District Court for the Southern District of New York or, if such claim, action, suit or proceeding cannot be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New York, Borough of Manhattan, and agrees not to bring any such claim, action, suit or proceeding in any other court. Each Party hereby waives, and agrees not to assert in any such claim, action, suit or proceeding, to the fullest extent permitted by Applicable Law, any claim that (i) such Party is not personally subject to the jurisdiction of such courts, (ii) such Party and such Party's property is immune from any legal process issued by such courts or (iii) any claim, action, suit or proceeding commenced in such courts is brought in an inconvenient forum. Each Party agrees that a final judgment in any such claim, action, suit or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Applicable Law. Each Party acknowledges and agrees that this Section 10.8(b) constitutes a voluntary and bargained-for agreement between the Parties.
- (c) The Parties agree that service of process in any claim, action, suit or proceeding referred to in Section 10.8(b) may be served on any Party anywhere in the world, including by sending or delivering a copy of such process to such Party in any manner provided for the giving of notices in Section 10.2. Nothing in this Purchase and Sale Agreement will affect the right of any Party to serve process in any other manner permitted by Applicable Law. Each Party waives personal service of any summons, complaint or other process, which may be made by any other means permitted by New York law.

Section 10.9 <u>Waiver of Jury Trial</u>. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS PURCHASE AND SALE AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER

THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HERETO HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE OTHER PARTY HERETO WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS PURCHASE AND SALE AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10.9.

Section 10.10 <u>Severability</u>. If one or more provisions of this Purchase and Sale Agreement are held to be invalid or unenforceable by a court of competent jurisdiction, such provision shall be excluded from this Purchase and Sale Agreement and the balance of this Purchase and Sale Agreement shall be interpreted as if such provision were so excluded and shall remain in full force and effect and be enforceable in accordance with its terms. Any provision of this Purchase and Sale Agreement held invalid or unenforceable only in part or degree by a court of competent jurisdiction shall remain in full force and effect to the extent not held invalid or unenforceable.

Section 10.11 <u>Counterparts</u>. This Purchase and Sale Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Purchase and Sale Agreement shall become effective when each Party shall have received a counterpart hereof signed by the other Party. Any counterpart may be executed by facsimile or other similar means of electronic transmission, including "PDF," and such facsimile or other electronic transmission shall be deemed an original.

Section 10.12 Amendments; No Waivers. Neither this Purchase and Sale Agreement nor any term or provision hereof may be amended, supplemented, restated, waived, changed or modified except with the written consent of the Parties. No failure or delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. No notice to or demand on any Party in any case shall entitle it to any notice or demand in similar or other circumstances. No waiver or approval hereunder shall, except as may otherwise be stated in such waiver or approval, be applicable to subsequent transactions. No waiver or approval hereunder shall require any similar or dissimilar waiver or approval thereafter to be granted hereunder. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

Section 10.13 No Third Party Rights. Other than the Parties, no Person will have any legal or equitable right, remedy or claim under or with respect to this Purchase and Sale Agreement or any of the other Transaction Documents. This Purchase and Sale Agreement may be amended or terminated, and any provision of this Purchase and Sale Agreement may be waived, without the consent of any Person who is not a Party. The Seller shall enforce any legal or equitable right, remedy or claim under or with respect to this Purchase and Sale Agreement for the benefit of the Seller Indemnified Parties and the Purchaser shall enforce any legal or equitable right, remedy or claim under or with respect to this Purchase and Sale Agreement for the benefit of the Purchaser Indemnified Parties.

Section 10.14 <u>Table of Contents and Headings</u>. The Table of Contents and headings of the Articles and Sections of this Purchase and Sale Agreement have been inserted for convenience of reference only, are not to be considered a part hereof and shall in no way modify or restrict any of the terms or provisions hereof.

{SIGNATURE PAGE FOLLOWS}

IN WITNESS WHEREOF, the Parties have executed this	Purchase and Sale Agreement as of the day and year first written above.
ATARA BIOTH	HERAPEUTICS, INC.
By:	/s/ Pascal Touchon Pascal Touchon President and Chief Executive Officer (Principal Executive Officer)

[Signature Page to Purchase and Sale Agreement]

IN WITNESS WHEREOF, the Parties have executed this Purchase and Sale Agreement as of the day and year first written above.

HCR MOLAG FUND, L.P.

By HCR Molag Fund GP, LLC, its General Partner

By:

/s/ Clarke B. Futch Clarke B. Futch Managing Partner

[Signature Page to Purchase and Sale Agreement]

#### Exhibit A

## Licensee Instruction [[\*\*\*]]

#### Exhibit B

#### Form of Bill of Sale

#### Exhibit D

#### **Commercialization Agreement**

Exhibit E

#### MSK Agreement

#### LIST OF SUBSIDIARIES

The following is a list of subsidiaries of the Company as of December 31, 2022:

Subsidiary Legal Name State or other Jurisdiction of Incorporation or Organization

Atara Biotherapeutics Australia Pty. Ltd.

Australia Ireland

Atara Biotherapeutics Ireland Limited Atara Biotherapeutics Switzerland GmbH

Switzerland

#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statements No. 333-19508, 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. 333-266288 on Form S-8 of our reports dated February 8, 2023, relating to the consolidated financial statements of Atara Biotherapeutics, Inc. and subsidiaries (the "Company") and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2022.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California February 8, 2023

## CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO

#### SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

- I, Pascal Touchon, certify that:
- 1.I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;
- 2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 8, 2023

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

## <u>CERTIFICATION OF THE CHIEF FINANCIAL OFFICER</u> <u>PURSUANT TO</u>

#### SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

- I, Utpal Koppikar, certify that:
- 1.I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;
- 2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 8, 2023

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

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in connection with the Annual Report of Atara Biotherapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the "Report"), Pascal Touchon, Chief Executive Officer of the Company, and Utpal Koppikar, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 8, 2023

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

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

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.