

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from _____ to _____
Commission File Number 001-36548

ATARA BIOTHERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction of incorporation or organization)
1280 Rancho Conejo Blvd

Thousand Oaks, CA
(Address of principal executive offices)

46-0920988
(I.R.S. Employer Identification No.)

91320
(Zip Code)

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

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

Title of each class
Common 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 to Section 12(g) of the Act: None

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the Registrant, based on the closing sales price for such stock on June 30, 2024 as reported by The Nasdaq Stock Market, was \$41,039,683. This calculation excludes 76,019 shares held by executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

The number of outstanding shares of the Registrant's Common Stock as of March 3, 2025 was 5,858,909.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

ATARA BIOTHERAPEUTICS, INC.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such forward-looking statements, which represent our intent, belief or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “predict,” “plan,” or “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 review of strategic alternatives;
- our expectations regarding our clinical studies, client sites, 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 expectations about the timing of approvals for a biologics license application (BLA) for tab-cel[®] for patients with Epstein-Barr virus with post-transplant lymphoproliferative disease (EBV+ PTLD);
- our ongoing discussions with Pierre Fabre Medicament related to the transition of all operational activities for tab-cel, except the BLA sponsorship, as early as the end of the first quarter of 2025;
- the potential indications for our product and product candidates;
- commercialization of tab-cel (Ebvallo[™] in the United Kingdom (UK), the European Economic Area (EEA) and Switzerland) worldwide and our amended and restated Commercialization Agreement with Pierre Fabre Medicament, including potential milestone and royalty payments under the agreement (Ebvallo in the UK, the EEA and Switzerland subject to the Purchase and Sale Agreement with HCR Molag Fund, L.P.);
- our Purchase and Sale Agreement and related transactions with HCR Molag Fund, L.P.;
- the wind-down of our Commercial Manufacturing Services Agreement with Charles River Laboratories, Inc. (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 going concern assessment;
- our ability to enter into favorable commercialization arrangements with third parties to commercialize our product candidates;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical studies;
- the initiation, timing, costs, progress, and results of clinical studies and our research and development programs;
- our ability to enter into and maintain contracts with clinical research organizations (CROs), contract manufacturing organizations (CMOs), and other vendors for clinical studies, supplies, and other services;
- the scope of protection we are able to obtain and maintain for the intellectual property rights covering our product and product candidates;
- our financial performance;
- our election to rely on reduced reporting and disclosure requirements available to smaller reporting companies;
- developments and projections relating to our competitors and our industry;
- our ability to have our product and product candidates manufactured for our clinical studies or for commercial sale, including at commercially reasonable values;
- the impact of public health emergencies to our business and operations, as well as the businesses and operations of third parties on which we rely;

- the impact of our workforce reductions on our ability to attract, retain, and motivate qualified personnel and on our business, operations, and financial condition; and
- timing and costs related to the qualification of the manufacturing facilities of our CMOs for commercial production.

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

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

Summary Risk Factors

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

- our activities to review and pursue strategic alternatives may not result in a strategic transaction, and even if we do consummate a strategic transaction, there is no assurance that it will deliver the benefits we expect or enhance stockholder value;
- our board of directors may determine to pursue a liquidation and dissolution or other wind down of our business, and in such event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities;
- we have incurred substantial losses since our inception and anticipate that we will continue to incur substantial losses for the foreseeable future;
- we have earned limited commercialization revenues to date, and we may never achieve profitability;
- we will require substantial near-term financing to continue operations, 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, or impair our exploration of strategic alternatives, or require us to pursue a liquidation and dissolution or other wind down of our business;
- we have one approved product, Ebvallo, in the EEA, the UK, and Switzerland. In March 2025, we announced our decision to pause the development of our allogeneic CAR-T cell programs and to discontinue all CAR-T operations. 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;
- our T-cell immunotherapy product and product candidates 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;
- the results of preclinical studies or earlier clinical studies are not necessarily predictive of future results, and our existing product candidates may not receive regulatory approval;
- clinical drug development involves a lengthy and expensive process with an uncertain outcome;
- there can be no assurance that we will achieve all of the anticipated benefits of the Fujifilm Transaction and we could face unanticipated challenges;
- the market opportunities for our product and product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small;
- we may not be able to obtain or maintain orphan drug exclusivity for our product candidates;

- the proposed revision of the European legislation on pharmaceuticals, changes in governmental administration, or changes in leadership at relevant regulatory agencies could lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU and US, including orphan medicinal products;
- if we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected;
- our principal stockholders own a significant percentage of our stock and will be able to exert control or significant influence over matters subject to stockholder approval;
- we qualify as a “smaller reporting company” and a “non-accelerated filer,” and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to such companies could make our stock less attractive to investors;
- our future success depends on our ability to retain our executive officers and to attract, retain, and motivate qualified personnel;
- our workforce reductions may not result in anticipated savings, could result in total costs and expenses that are greater than expected, and could disrupt our business; and
- maintaining clinical and commercial timelines is dependent on our end-to-end supply chain network to support manufacturing; if we experience problems with our third party suppliers or CMOs, development and/or commercialization of our product and product candidates may be adversely affected.

PART I

Item 1. Business

Overview

Atara Biotherapeutics is a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune disease. Tab-cel (tabelecleucel), our lead program in Phase 3 clinical development in the U.S., has received marketing authorization approval (MAA) under the proprietary name Ebvallo™ for commercial sale in the European Economic Area (EEA) by the European Commission (EC), for commercial sale and use in the United Kingdom (UK) by the Medicines and Healthcare products Regulatory Agency (MHRA), and for commercial sale and use in Switzerland by Swissmedic. 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). Our strategic priority is:

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

In addition to the aforementioned strategic priority, we also have ATA3219, an allogeneic CAR T targeting CD19 intended to target B-cell malignancies and autoimmune diseases, based on a next generation 1XX signaling domain and the innate advantages of EBV T cells as the foundation for an allogeneic CAR T platform, and ATA3431, an allogeneic dual CAR T immunotherapy targeting both CD19 and CD20 for B-cell malignancies; and a potential next generation EBV vaccine which is differentiated from earlier EBV vaccine efforts that solely focused on B cell responses to EBV. In March 2025, we announced our decision to pause the development of our allogeneic CAR-T cell programs and to discontinue all CAR T operations for ATA3219 and ATA3431, including terminating the clinical trials evaluating ATA3219. We expect to complete wind-down activities for the CAR T programs by the end of the first quarter of 2025.

Our T-cell immunotherapy platform is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. We select the appropriate set of cells for use based on a patient's unique immune profile. Both of our contract manufacturing organizations (CMOs) have completed commercial production qualification activities for tab-cel commercialization in the EEA and are in the process of completing commercial production qualification activities in the US. We continue to manufacture inventory according to Pierre Fabre's commercial product supply strategy.

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

On October 31, 2023, we entered into an amended and restated Pierre Fabre Commercialization Agreement (A&R Commercialization Agreement), pursuant to which we expanded Pierre Fabre's exclusive rights to research, develop, manufacture,

commercialize and distribute tab-cel (Ebvallo) to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of \$20.0 million for the expanded exclusive license grant, for which the cash was received in January 2024. In March 2024, we met the contractual right to receive \$20.0 million in milestone payments upon achieving a regulatory milestone, for which the cash was received in April 2024. In July 2024, we met the contractual right to receive an additional \$20.0 million in milestone payments upon achieving acceptance of our biologics license application (BLA) for tab-cel by the United States Food and Drug Administration (FDA) and we received the cash in August 2024. We will also be entitled to receive an aggregate of up to \$580.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory including up to \$60.0 million in potential regulatory milestones in connection with the approval by the FDA of a BLA for tab-cel. We are eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel in each such country. Royalty payments may be reduced in certain specified customary circumstances. Royalties and milestones from the commercialization of Ebvallo in the Initial Territory remain subject to the HCRx Agreement.

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

Prior to the transfer of manufacturing responsibility to Pierre Fabre, we will be responsible for manufacturing and supplying tab-cel to Pierre Fabre for commercialization in the Territory at cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab-cel in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of i) the date on which all activities relating to the transfer of tab-cel manufacturing, pursuant to the A&R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, throughout the remainder of the term of the A&R Commercialization Agreement. We and Pierre Fabre are to use commercially reasonable efforts to achieve this prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the first BLA. We are in active discussions with Pierre Fabre on accelerating transfer of all operational activities related to tab-cel, except the BLA sponsorship, to be completed as early as the end of the first quarter of 2025, as well as assumption by Pierre Fabre of certain costs related to the remediation of the third party manufacturing facility to address the FDA's requests in order to lift the clinical hold and to support resubmission of the BLA for tab-cel. As part of these discussions, we expect to agree to reduce the amount of certain future potential regulatory and commercial milestone payments relating to tab-cel in the Additional Territory. Any delays in completing the manufacturing transfer to Pierre Fabre will result in us being responsible for supplying tab-cel to Pierre Fabre until the completion of the transfer which will cause us to incur additional costs in order to meet our supply obligations.

In August 2024, we sold certain intermediates used in the manufacture of Ebvallo to Pierre Fabre for \$15.5 million, transferring title and risk of loss to these intermediates in advance of the Manufacturing Transition Date. We received payment for these intermediates in September 2024.

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

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

We and FUJIFILM Diosynth Biotechnologies California, Inc. (FDB) entered into a Master Services and Supply Agreement (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 cell therapy products (if approved) and product candidates, manufactured in accordance with cGMP standards. The Fujifilm MSA does not obligate us to purchase products and product candidates exclusively from FDB.

We also worked with Charles River Laboratories (CRL) pursuant to a Commercial Manufacturing Services Agreement (CRL MSA) that we entered into in December 2019. CRL provided manufacturing services for our product and certain intermediates under the CRL MSA. The CRL MSA expired on August 31, 2024 and we are currently in negotiations with CRL for a statement of work to support an orderly wind-down of manufacturing activities at CRL, transition of manufacturing activities of certain intermediates to FDB, and an orderly transition of manufacturing responsibility to PF upon the Manufacturing Transition Date.

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

In November 2023, we announced a reduction in force of approximately 30% of our workforce at that time. This workforce reduction resulted in total restructuring charges of \$6.7 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California Worker Adjustment and Retraining Notification (WARN) Act. In most cases, the severance payments were paid as a lump sum in January 2024. All of the severance costs represent cash expenditures. As of December 31, 2024, there are no remaining payments for the November 2023 reduction in workforce. All of the costs were cash expenditures and represent one-time termination benefits.

In January 2024, we announced a strategic reduction in workforce of approximately 25%. The workforce reduction resulted in total restructuring charges of \$5.1 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance payments were paid during the first half of 2024. Certain of the notified employees had employment agreements that provided for separation benefits in the form of salary continuation, which were paid from February 2024 through January 2025. As of December 31, 2024, approximately \$0.1 million of further separation payments and benefits are required for the January 2024 reduction in workforce. The majority of the associated costs are cash expenditures and primarily represent one-time termination benefits.

In January 2025, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (Response Letter) for the Biologics License Application (BLA) for tab-cel as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLTD), who have received at least one prior therapy including an anti-CD20 containing regimen. The Response Letter only cited findings that arose during a pre-license inspection of a third-party manufacturing facility for tab-cel. The Response Letter did not identify any deficiencies related to the manufacturing process, the clinical efficacy, or clinical safety data in the BLA, and the FDA did not request any new clinical trials to support a potential approval of tab-cel. Additionally, in January 2025, the FDA placed a clinical hold on Atara's active Investigational New Drug (IND) applications. These INDs include the tab-cel program as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLTD). The clinical hold is directly linked to inadequately addressed Good Manufacturing Practices (GMP) compliance issues referenced in the Response Letter. We are currently undertaking efforts to support this third-party manufacturer in addressing the FDA's requests to lift the clinical hold and to support resubmission of the BLA for tab-cel.

In January 2025, we announced another strategic reduction in workforce of approximately 50%. We expect to recognize approximately \$7.5 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2025. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from April 2025 through May 2026. The majority of the associated costs represent cash expenditures.

In March 2025, we announced a further strategic reduction in workforce of approximately 50%, retaining approximately 35 employees essential to executing on our strategic priorities. We expect to recognize approximately \$3.0 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2025. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from May 2025 through May 2026. The majority of the associated costs represent cash expenditures.

Review of Strategic Alternatives

Our board of directors regularly reviews Atara's strategic plan, priorities, and opportunities as part of its commitment to act in the best interest of Atara and its stockholders. In January 2025, we announced that we had previously engaged a well-known financial advisor to support the assessment of opportunities to advance and realize value from Atara's CAR-T assets, for which we announced that we have subsequently paused development in March 2025. The advisor's scope was expanded to include a wider range of additional strategic alternatives which may include, but are not limited to, an acquisition, merger, reverse merger, other business combinations, sale of assets, or other strategic transactions. Through this process, we are in active discussions with several potential

parties. However, there can be no assurance regarding the results or outcome of this process. It is possible that we may not pursue a strategic alternative or transaction or that any strategic alternative or transaction, if pursued, it will not be completed on attractive terms, or that a strategic alternative or transaction may not ultimately be consummated.

Pipeline

Our pipeline is summarized below:

Program	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Status
Tab-cel® or Eivallo™ (tabellecleucel)	RR EBV+ PTLD following HCT and SOT*	EBV	ALLELE Study				EU Approved	Addressing FDA requests to lift clinical hold and support BLA resubmission
	Multi-Cohort (Label-Expansion): EBV+ cancers ⁽¹⁾	EBV	EBVision Study					
ATA3219 (Oncology)	Non-Hodgkin's Lymphoma (NHL)	CD19	[Progressing]					Paused
ATA3219 (Autoimmune)	Lupus Nephritis (LN)	CD19	[Progressing]					Paused
	Lupus Nephritis (LN) Extrarenal Systemic Lupus Erythematosus (SLE) without lymphodepletion		[Progressing]					Paused
ATA3431	B-cell malignancies	CD19/CD20	[Progressing]					Paused
	Autoimmune disease		[Progressing]					

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

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

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

*Indication pursued as monotherapy for treatment of adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate

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

Eivallo™ (Tab-cel®)

EBV+ PTLD

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

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

Tab-cel® (Eivallo™) for EBV+ PTLD

In June 2015, we licensed certain patent rights, know-how and a library of T cells and cell lines specific to EBV from MSK under an exclusive license agreement. In accordance with the license agreement, we agreed to use commercially reasonable efforts to commercialize the licensed products and to make milestone payments with respect to the licensed programs and to make royalty

payments to MSK to the extent product candidates arising from the collaboration are commercialized. Our first commercial product, Ebvallo, is part of this MSK collaboration and targets EBV.

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

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

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

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

In the third quarter of 2020, we completed an interim analysis for the ALLELE study. Data from the interim analysis showed a 50 percent objective response rate (ORR) to tab-cel with independent oncologic and radiographic assessment (IORA) in patients with relapsed-refractory EBV+ PTLD following HCT or SOT, that had reached at least six months follow-up after the ORR assessment. This ORR is consistent with previously published investigator assessed data. The tab-cel safety profile is also consistent with previously published data, with no new safety signals. In December 2022, we presented updated interim analysis and safety results from the ALLELE study and updated efficacy and safety data from two single-center, open-label studies, and multicenter expanded access program in patients with EBV+ Leiomyosarcomas at the 2022 American Society of Hematology Annual Meeting. In December 2023, we presented new data for patients with relapsed or refractory (r/r) or treatment-naïve EBV+ PTLD involving the central nervous system following SOT or HCT. An ORR of 77.8% was observed in 18 central nervous system (CNS) EBV+ PTLD patients including first line PTLD, and the estimated one-year overall survival rate (OS) was 70.6%. The one-year OS for responders was 85.7% versus 0% for non-responders. In January 2024, data from the ALLELE study that was published in *The Lancet Oncology* showed a 51.2% objective response rate and 23-month median duration of response in r/r EBV+ PTLD patients and that tab-cel was well tolerated with no events of graft-versus-host disease as related to tab-cel. In May 2024, we filed the BLA with the FDA using a more recent data cutoff in the BLA submission package, data from the submission package showed similar ORR of 48.8% was demonstrated among patients in the indicated target population, consistent with previous analyses.

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

On October 31, 2023, we entered into the A&R Commercialization Agreement, which became effective in December 2023. Pursuant to the A&R Commercialization Agreement, Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute tab-cel (Ebvallo) will be expanded to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of \$20.0 million for the expanded exclusive license grant, for which such cash was received in January 2024. In March 2024, we met the contractual right to receive \$20.0 million in milestone payments upon achieving a regulatory milestone, for which the cash was received in April 2024. In July 2024, we met the contractual right to receive an additional \$20.0 million in milestone payments.

upon achieving acceptance of our biologics license application (BLA) for tab-cel by the United States Food and Drug Administration (FDA) and we received the cash in August 2024. We will also be entitled to receive an aggregate of up to \$580.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory including up to \$60.0 million in potential regulatory milestones in connection with the approval by the FDA of a BLA for tab-cel. We are in active discussions with Pierre Fabre on accelerating the transfer of all operational activities related to tab-cel, except the BLA sponsorship, to be completed as early as the end of the first quarter of 2025, as well as assumption by Pierre Fabre of certain costs related to the remediation of the third party manufacturing facility to address the FDA's requests in order to lift the clinical hold and to support resubmission of the BLA for tab-cel. As part of these discussions, we expect to agree to reduce the amount of certain future potential regulatory and commercial milestone payments relating to tab-cel in the Additional Territory.

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

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

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

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

In May 2024, we filed the BLA with the FDA. In July 2024, the FDA accepted the BLA submission and granted priority review with a Prescription Drug User Fee Act target action date of January 15, 2025. In January 2025, we received the Response Letter from the FDA regarding our BLA. The Response Letter was solely related to observations as part of a standard pre-license inspection of a third-party manufacturing facility for EBVALLO. The Response Letter did not identify any deficiencies related to the manufacturing process, the clinical efficacy, or clinical safety data in the BLA, and the FDA did not request any new clinical trials to support a potential approval of tab-cel.

In January 2025, the FDA placed a clinical hold on Atara's active Investigational New Drug (IND) applications. These INDs include the tab-cel program as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD). The clinical hold is directly linked to inadequately addressed GMP compliance issues referenced in the Response Letter. While ATA3219 drug product is manufactured at a separate facility, the starting materials used in its production are affected by the compliance issues at the same third-party facility referenced in the Response Letter. We are currently undertaking efforts to support this third-party manufacturer in addressing the FDA's requests to lift the clinical hold and to support resubmission of the BLA for tab-cel.

Tab-cel Multi-Cohort Study

In patients where previous treatments have failed, the objective response rates, including complete response, were 33.3% (three out of nine patients) in AID-LPD and 37.5% (three out of eight patients) in PID-LPD groups. Tab-cel was generally well-tolerated with a favorable safety profile consistent with previously published clinical studies. These clinical data demonstrated that tab-cel was

well-tolerated and showed encouraging clinical activity in this patient population, with objective response rates ranging from 50% (two out of four patients) to 80% (four out of five patients). The overall survival (OS) rate at one year in patients with EBV viremia treated in the EAP-201 study was 100 percent for a median follow-up of 14.6 months (min 12.2, max 17.8).

In the third quarter of 2020, we initiated a Phase 2 multi-cohort study which comprises a total of five patient populations, including IA-LPDs and other EBV-driven diseases, in both the U.S. and EU. In January 2025, the FDA placed a clinical hold on Atara's active Investigational New Drug (IND) applications. These INDs include the tab-cel multi-cohort study. The clinical hold is directly linked to inadequately addressed Good Manufacturing Practices (GMP) compliance issues referenced in the Response Letter. We plan to continue to enroll patients in this study once the clinical hold is lifted.

In December 2023, we presented combined analysis that included the first reported data from our Phase 2 multi-cohort study at the European Society for Medical Oncology Immuno-Oncology annual congress that demonstrated a 77.8% ORR in 18 CNS EBV+ PTLN patients including first line PTLN.

ATA3219

ATA3219 is a potential best-in-class, allogeneic CD19 CAR T immunotherapy targeting B-cell malignancies and autoimmune diseases, leveraging our next-generation 1XX CAR co-stimulatory domain and EBV T-cell platform and does not require TCR or HLA gene editing. ATA3219 combines the natural biology of unedited T cells with the benefits of an allogeneic therapy. It consists of allogeneic EBV-sensitized T cells that express a CD19 CAR construct for the treatment of CD19+ r/rB-cell malignancies, including B-cell non-Hodgkin's lymphoma (NHL) and B-cell mediated autoimmune diseases including systemic lupus erythematosus (SLE) with kidney involvement (lupus nephritis (LN)). ATA3219 has been optimized to offer a potential best-in-class profile, featuring off-the-shelf availability. It incorporates multiple clinically validated technologies including a modified CD3 ζ signaling domain (1XX) that optimizes expansion and mitigates exhaustion, provides enrichment during manufacturing for a less differentiated phenotype for robust expansion and persistence and retains the endogenous T-cell receptor without gene editing as a key survival signal for T cells which contribute to persistence.

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

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

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

Data from an academic study (Curran et al ASH 2023) that used allogeneic EBV CAR T cells (CD28/CD3 ζ co-stimulatory domain), demonstrated proof of principle for Atara's allogeneic CAR T approach with overall survival up to 3 years in post-transplant B-cell malignancy patients. Atara's ATA3219 builds upon this study with an improved process and construct that leverages multiple clinically validated technologies featuring a less differentiated phenotype and a novel 1XX costimulatory domain.

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

In February 2024, we received a Safe to Proceed letter from the FDA in response to our IND submission for use of ATA3219 as a monotherapy for the treatment of SLE with LN. In July 2024, we expanded this Phase 1 study to add a new cohort in extrarenal SLE without lymphodepletion (LD). The elimination of LD is designed to further simplify the treatment regimen and to potentially provide a differentiated safety profile to patients without compromising efficacy which may improve patient access.

In January 2025, the FDA placed a clinical hold on Atara's active IND applications. These INDs include ATA3219 for the treatment of non-Hodgkin's lymphoma and systemic lupus erythematosus. The clinical hold is directly linked to inadequately addressed GMP compliance issues referenced in the Response Letter. While ATA3219 drug product is manufactured at a separate

facility, the starting materials used in its production are affected by the compliance issues at the same third-party facility referenced in the Response Letter.

In March 2025, we announced our decision to pause the development of our allogeneic CAR-T cell programs and to discontinue all CAR T operations, including terminating the clinical trials evaluating ATA3219. We expect to complete wind-down activities for the ATA3219 program by the end of the first quarter of 2025.

Additional Programs

ATA3431 is an allogeneic, bispecific CAR directed against CD19 and CD20 for B-cell malignancies and autoimmune disease, leveraging our 1XX CAR co-stimulatory domain and EBV T-cell platform and does not require gene TCR or HLA gene editing. Preclinical data presented at the American Society of Hematology 2023 demonstrated potential for potent antitumor activity, long-term persistence, and superior tumor growth inhibition compared to an autologous CD19/CD20 CAR T benchmark. In March 2025, we announced our decision to pause the development of our allogeneic CAR-T cell programs and discontinue all development operations, including ATA3431. We expect to complete wind-down activities for the ATA3431 program by the end of the first quarter of 2025.

We have also discontinued some programs and will return the programs to our collaborators. For example, in March 2024, we returned the ATA2271 and ATA3271 programs targeting mesothelin to MSK. We are in discussions with QIMR Berghofer to return rights to ATA188 and the EBV vaccine to QIMR Berghofer.

We believe our platform will have utility beyond the current set of targets to which it has been directed.

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 have significantly greater established presences in the market, financial resources, varied technologies, scientific tools and technical expertise than we do. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient for the patient, 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 relapsed and/or refractory 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.

CAR T Program

There are currently six autologous CAR T therapies approved in the U.S. and/or EU. 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.

Terms of Certain License and Collaboration Agreements

Out-licensing

Pierre Fabre Commercialization Agreement

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

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

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

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

Pierre Fabre paid us an upfront cash payment of \$45.0 million for the exclusive license grant for the Initial Territory in the fourth quarter of 2021. In December 2022, we met the contractual right to receive \$40.0 million in milestone payments upon certain regulatory milestones, for which the cash was received in January 2023. Subject to the terms of the royalty purchase agreement with HCRx, as described in Note 6 – “Liability Related to the Sale of Future Revenues” in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report, we are entitled to receive an aggregate of up to \$308.0 million in remaining milestone payments upon achieving certain regulatory and commercial milestones in addition to double-digit tiered royalties as a percentage of net sales of Ebvallo in the Initial Territory, until the later of 12 years after the first commercial sale in such country, the expiration of specified patent rights, or the expiration of all regulatory exclusivity for such product on a country-by-country basis. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of \$20.0 million for the expanded exclusive license grant, for which the cash was received in January 2024. In March 2024, we met the contractual right to receive \$20.0 million in milestone payments upon achieving a regulatory milestone, for which the cash was received in April 2024. In July 2024, we met the contractual right to receive an additional \$20.0 million in milestone payments upon achieving acceptance of our biologics license application (BLA) for tab-cel by the United States Food and Drug Administration (FDA) and we received the cash in August 2024. We will also be entitled to receive an aggregate of up to \$580.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory, including up to \$60.0 million in potential regulatory milestones through the approval by the FDA of a BLA for tab-cel. In addition, we will be eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Additional Territory until the later of 12 years after the first commercial sale in such country, the expiration of specified patent rights in such country, or the expiration of all regulatory exclusivity for such Product in such country.

We have entered into a separate manufacturing and supply agreement with Pierre Fabre for us to manufacture Ebvallo for Pierre Fabre to use in the Initial Territory based on a fixed price through December 31, 2023 and at a price equal to cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Prior to the transfer of manufacturing responsibility to Pierre Fabre, we will be responsible for manufacturing and supplying tab-cel to Pierre Fabre for commercialization in the Territory. Upon the Manufacturing Transition Date and through the remainder of the term of the A&R Commercialization Agreement, Pierre

Fabre will be responsible, at its cost, for the manufacture and supply of tab-cel in the Territory. Without transfer of the manufacturing technology, no other party can manufacture tab-cel.

In February 2025, we transferred commercial cell selection in the Initial Territory and the Additional Territory to Pierre Fabre. Until the transition of clinical cell selection to Pierre Fabre is complete, we will continue to perform cell selection services in support of global clinical activities, at the expense of Pierre Fabre. Cell selection is the process of identifying the appropriate cell line from available inventory to be used for a patient.

In-licensing

MSK Agreements

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

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

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

In March 2024, we terminated our license agreements with MSK to the ATA2271 and ATA3271 programs targeting mesothelin.

During the third quarter of 2024, MSK sent us a notice alleging that under the terms of our license agreements with MSK, MSK is entitled to \$6.0 million of sub-licensing fees as a result of the \$60.0 million we received from Pierre Fabre related to the Additional Territory upfront and milestone payments in 2024 pursuant to the A&R Commercialization Agreement. We do not believe we owe the \$6.0 million to MSK under the terms of our license agreements with MSK and are participating in evaluative non-binding mediation with MSK to potentially resolve this disagreement. We paid the \$6.0 million to MSK under protest in the third quarter of 2024 in order to proceed with the dispute process per the terms of the license agreements. We recorded this cost in research and development expenses on the consolidated statements of operations and comprehensive income (loss) during the year ended December 31, 2024. There is no guarantee we will reach a favorable outcome in the mediation or on this matter and we may owe a portion of future milestones we receive from Pierre Fabre to MSK.

QIMR Berghofer Agreements

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

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

In December 2024, we began discussions with QIMR Berghofer to return the rights to ATA188 and the EBV vaccine to QIMR Berghofer.

Intellectual Property

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

Patents

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

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

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

product candidates, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

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

Trade Secrets

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

Trademarks

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

Government Regulation and Product Approval

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

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

U.S. Product Development Process

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

judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices (GLPs), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB), or ethics committee at each clinical site before the trial is commenced at such clinical site;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as good clinical practices (GCPs), and any additional requirements for the protection of human research patients and their health information to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency of the drug from analytical (CMC) studies and from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced and tested to assess compliance with cGMP; to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and; if applicable, to assess compliance with 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 drug 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. Nonclinical testing often continues even after an IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to unacceptable and significant risks to clinical trial subjects or non-compliance with FDA requirements. If the FDA imposes a clinical hold, trials may not begin, continue or recommence in the U.S. without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate the conduct of such trials in the U.S.

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

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

- Phase 1.* The biological product is initially introduced into human subjects and tested primarily for safety. Healthy human subjects can be used in these initial trials, although 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 conducted in patients rather than healthy human volunteers.
- Phase 2.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for marketing approval and product labeling.

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

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

U.S. BLA Review and Approval Processes

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

Under the Prescription Drug User Fee Act, as amended (PDUFA), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for 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. REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit and obtain approval for a proposed REMS. The FDA will not approve a BLA without a REMS, if the FDA deems a REMS is required for the safe use of the drug.

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

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA after its review, the FDA will issue a complete response letter that describes the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, manufacturing issues or 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 some cases, the FDA may approve a product conditionally through a mechanism called accelerated approval. While this mechanism allows for patient access to a treatment based 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, the approval is conditional as a condition of approval, a sponsor of a drug or biological product receiving accelerated approval will be required to perform adequate and well-controlled post-marketing clinical studies to affirm a clinical benefit.

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

Orphan Drug Designation in the U.S.

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

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

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

Expedited Development and Review Programs in the U.S.

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address an unmet medical need for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. For a product that has received fast track designation, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted. A sponsor seeking a rolling submission must provide a schedule for the submission of each section of the BLA, and the FDA must agree to the rolling submission and that the schedule is acceptable. In addition, the sponsor must pay any required user fees upon submission of the first section of the BLA. Submission of sections of a BLA on a rolling basis does not guarantee that the FDA will begin their review of these sections upon receipt or even before the BLA submission is deemed to be complete. Therefore, a rolling BLA submission may not result in a faster timeline to marketing approval. Additionally, a rolling BLA submission has no bearing on whether or not a product candidate is ultimately approved.

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

Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, but is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. Approval under this pathway takes 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 implementation. Other types of changes to the approved product, such as adding new indications and claims, are also subject to 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. New safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and/or contraindications, and also may require the implementation of other risk management measures, for example, a REMS. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Regulatory Exclusivity for Biologics

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

The BPCIA 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 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, and could require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third party payors will decide with respect to coverage and reimbursement for our drug products.

These third party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. The containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In the U.S. there have been several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, included in the Consolidated Appropriations Act of 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the Departments of Health and Human Services, Labor and the Treasury. In August 2022, former President Biden signed into law the Inflation Reduction Act of 2022 (IRA), which implements substantial changes to the Medicare program, including drug pricing reforms and changes to the Medicare Part D benefit design. Among other reforms, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap benefit annual out-of-pocket spending at \$2,000 while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services (CMS). CMS has also taken steps to implement the IRA, including: releasing the negotiated maximum prices, which will be effective in 2026, for the first ten drugs that were subject to the IRA's negotiation process, releasing quarterly lists of Medicare Part B products that are subject to adjusted coinsurance rates based on the inflationary rebate provisions of the IRA, and announcing a list of fifteen additional drugs that will be subject to price negotiations during 2025. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services (HHS), the Secretary of HHS, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions.

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. For example, several state laws require disclosures to state agencies and/or commercial purchasers with respect to price increases and new product launches that exceed certain pricing thresholds as identified in the relevant statutes. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Some states have also established prescription drug affordability boards that are tasked with identifying certain high-cost prescription products that may pose affordability challenges for consumers and payers, conducting cost reviews on such products, and, in some circumstances, imposing upper payment limits on such products.

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 health insurance program that is administered by the states for eligible low-income adults, children, families, pregnant women, and people with certain disabilities. In order to ensure states receive federal matching funds for outpatient drugs furnished to Medicaid patients, pharmaceutical manufacturers must participate in the Medicaid Drug Rebate Program, which requires manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS. Under the Medicaid Drug Rebate Program, manufacturers are required to pay a rebate to each state Medicaid program for each unit of a covered outpatient drug reimbursed by the state Medicaid programs. Medicaid Drug Rebate Program rebates are calculated using a statutory formula, state-reported utilization data, and pricing data that are calculated and reported by manufacturers on a monthly and quarterly basis to CMS. These data include the average manufacturer price (AMP) and, in the case of single source and innovator multiple source products, the best price for each drug. Manufacturer rebates may further increase if certain pricing metrics increase 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 Act 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. The IRA extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which the U.S. federal government covers particular healthcare products and services and could limit the amounts that the U.S. federal government will pay for healthcare products and services. This could result in reduced demand for our product candidates or additional pricing pressures.

The results of the 2024 Presidential and Congressional election, and potential subsequent developments further increase the uncertainty related to the healthcare regulatory environment, particularly given the Trump Administration's stated commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS and CMS. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by CMS and other agencies with significant oversight of the healthcare industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies may be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts that are difficult to predict but could have a material adverse effect on our business and financial condition. For example, certain of these changes could impose additional limitations on the rates we will be able to charge for our future products or the amounts of reimbursement available for our future products from governmental agencies or third-party payors.

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 of 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 as an intent-based federal criminal statute that prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, paying 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. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if any "one purpose" of an arrangement involving remuneration is to induce referrals of federal healthcare program business, the federal Anti-Kickback Statute has been violated. The federal Anti-Kickback Statute applies to arrangements between pharmaceutical manufacturers on the one hand and individuals, such as prescribers, patients, purchasers, and formulary managers on the other hand, including, for example, consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings, among others. A violation of the federal Anti-Kickback Statute includes per violation civil monetary penalties and significant criminal fines under the statute, additional civil penalties and treble damages under the False Claims Act, as discussed in more detail below, possible imprisonment, and mandatory exclusion from participation in the federal healthcare programs, meaning that federal healthcare programs would no longer reimburse (directly or indirectly) for products or services furnished by the excluded entity or individuals. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute that protect certain common industry activities from prosecution, these exceptions and safe harbors are narrowly drawn. Arrangements that do not fully satisfy all elements of an available exception or safe harbor are evaluated based on the specific facts and circumstances and are typically subject to increased scrutiny;

•Federal civil and criminal false claims laws, including the civil False Claims Act (FCA), which can be enforced through civil whistleblower or qui tam actions and prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Pharmaceutical manufacturers have been investigated and/or subject to government enforcement actions asserting liability under the FCA for a variety of alleged activities, including alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. Additionally, the Affordable Care Act specified that any claims submitted as a result of a violation of the federal Anti-Kickback Statute constitute false claims and are subject to enforcement under the FCA, and the government may further assert that a claim that includes items or services resulting from a violation of the FDCA or other law constitutes a false or fraudulent claim for purposes of the FCA;

•Federal civil monetary penalty laws, which impose significant civil penalties against individuals or entities that engage in activities including, among other things, knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; violations of the federal Anti-Kickback Statute; failing to report and return a known overpayment; or offering or transferring any remuneration to a Medicare or Medicaid beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of items or services reimbursable by Medicare or Medicaid, unless an exception applies;

•The FDCA and PHS Act, 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 knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully preventing, obstructing, misleading, or delaying a criminal investigation of a healthcare offense; and 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. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•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 for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, among others, to track and 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. Failure to timely, accurately, and completely submit the required information for all payments, transfers of value, and ownership or investment interested may result in civil monetary penalties;

•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 amended by the California Privacy Rights Act of 2020 (CPRA);
- State laws that require the reporting of certain pricing information, including information pertaining to and justifying price increases, prohibit prescription drug price gouging; or impose payment caps on certain pharmaceutical products deemed by the state to be “high cost”; and
- Similar healthcare and privacy laws and regulations in the European Economic Area (EEA), the UK and other jurisdictions, such as, the General Data Protection Regulation (EU) 2016/679, which impose obligations and restrictions on the collection and use of personal information relating to individuals located in the EEA and the UK (including health information).

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

Foreign Regulation

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

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

Under the CTR, clinical trial sponsors were able to, but not obligated to, use the CTIS starting January 31, 2022. Beginning January 31, 2023, clinical trial sponsors were required to use the CTIS to submit a CTA for a new clinical trial in the EU or EEA, but clinical trials already approved under the previous law, the Clinical Trials Directive (CTD) can continue running under the CTD until January 31, 2025. By this date, all CTAs originally approved under the CTD must have been transitioned to CTIS. National regulators in the EU Member States and EEA countries began to carry out their legal responsibilities in evaluating and overseeing clinical trials using the CTIS beginning January 31, 2022.

Under EU regulatory systems, a company may submit Marketing Authorization Applications (MAA) under national, centralized or decentralized, or mutual-recognition procedures. We expect to utilize the centralized procedure, which is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the EMA,

where it is evaluated by the Committee for Medicinal Products for Human Use. If this committee delivers a favorable opinion, this typically results in the grant by the EC of a single marketing authorization that is valid for all EU member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period.

Conditional marketing authorization in the EU is permitted based on incomplete clinical data for a limited number of medicinal products for human use, including products designated as orphan medicinal products under EU law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical study data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions. A different marketing authorization pathway, called “exceptional circumstances” is also available to sponsors; under the exceptional circumstances pathway, the EC grants marketing authorization of a product for a specific condition or disease when comprehensive data cannot be obtained even after authorization (e.g., for rare conditions or diseases). Sponsors who obtain marketing authorization for a drug product under exceptional circumstances are subject to ongoing post-marketing obligations to continue confirmation of the benefits of the product. Continuation of a marketing authorization granted under the “exceptional circumstances” regulatory pathway is subject to annual re-assessments. The annual re-assessment will determine whether the marketing authorization should be maintained, changed, or suspended, based on a sponsor’s fulfillment of its post-marketing obligations and the risk/benefit profile of product.

As in the U.S., we may apply for designation of a product as an orphan drug for the treatment of a specific indication in the EU before the MAA is submitted. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 11 years of orphan market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan-designated product.

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

Outside the U.S., there are additional challenges in ensuring adequate coverage and payment for our products. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory approval for a product and may require us to conduct a clinical study that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of this type of clinical study could be expensive and result in delays to our or our commercialization partners’ commercialization efforts. Third party payors are challenging the prices charged for medical products and services, and many third party payors limit reimbursement for newly-approved health care products. Budgetary pressures in many EU countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country with price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

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

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

Brexit and the Regulatory Framework in the United Kingdom

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

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

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

Orphan designation in Great Britain following Brexit is granted on an essentially identical basis as it is in the EU, but is based on the prevalence of the condition in Great Britain. It is therefore possible that conditions previously designated as an orphan condition in the EU, prior to Brexit, may no longer be designated as an orphan condition in Great Britain and that conditions that were not currently designated as orphan conditions in the EU prior to Brexit 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 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, and local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by, our operations. Our research and development involve the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and any such liability could exceed our resources.

Manufacturing

In April 2022, we sold all of our right, title and interest in and to certain assets related to the Atara T-Cell Operations and Manufacturing facility (ATOM Facility) located in Thousand Oaks, California to FDB. We also entered into a Master Services and Supply Agreement with FDB (Fujifilm MSA) which became effective in April 2022 and could extend for up to ten years. Pursuant to the Fujifilm MSA, FDB will supply us with specified quantities of our product and product candidates, manufactured in accordance with cGMP standards. The Fujifilm MSA does not obligate us to purchase our product and product candidates exclusively from FDB.

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

In addition to FDB, we also worked with Charles River Laboratories Inc. (CRL) pursuant to a Commercial Manufacturing Services Agreement (CRL MSA) that we entered into in December 2019. The CRL MSA expired on August 31, 2024 and we are currently in negotiations with CRL for a statement of work to support an orderly wind-down of manufacturing activities at CRL, transition of manufacturing activities of certain intermediates to FDB, and an orderly transition of manufacturing responsibility to PF upon the Manufacturing Transition Date.

Our current manufacturing strategy is to evaluate each product candidate and determine which site in our manufacturing network provides the phase-appropriate technical, quality and regulatory compliance requirements. In addition, the long-range supply requirements of our product candidates are evaluated periodically to ensure we are planning manufacturing capacity and capabilities accordingly across our network. Our manufacturing network is comprised of our own laboratory facilities and contract manufacturing organizations (CMOs). 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 (CFR) 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 and commercial drug supply. These include materials to support the manufacturing of clinical study and commercial material, including key starting materials and intermediates as well as existing inventory of clinical study and commercial 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, 2024, we had 153 employees. In January 2025, we announced a reduction in our workforce impacting approximately 50% of our employees. In March 2025, we announced a further reduction in our workforce impacting approximately 50% of our remaining workforce, after which we anticipate retaining approximately 35 personnel essential to execute on our remaining transition activities with Pierre Fabre and certain wind-down activities for our CAR-T programs. 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.

Corporate Information

We were incorporated in Delaware in 2012. Our principal corporate offices are located at 1280 Rancho Conejo Blvd., 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, Capital Needs, and Review of Strategic Alternatives

Our activities to review and pursue strategic alternatives may not result in a strategic transaction, and even if we do consummate a strategic transaction, there is no assurance that it will deliver the benefits we expect or enhance stockholder value.

In January 2025, we announced that our board of directors has initiated a process to explore a range of strategic alternatives to maximize value for our stockholders. We previously engaged a well-known financial advisor to support the assessment of opportunities to advance and realize value from our CAR-T assets, for which we announced that we have since paused the CAR T programs and discontinued development operations in March 2025. The advisor's scope was expanded to include a wider range of additional strategic alternatives, which may include, but are not limited to, an acquisition, merger, reverse merger, other business combinations, sale of assets, or other strategic transactions. We are actively in discussions with several potential parties.

We have not set a definitive timetable for completion of this process, and there can be no assurance regarding the results or outcome of this process. It is possible that we may not pursue a strategic alternative as a result of this process, that a strategic alternative that has been pursued may not be attractive, or that a strategic alternative may not ultimately be consummated. As part of the process, our board of directors will consider a full range of strategic alternatives, including, but not limited to, those identified in range of strategic alternative described above.

We expect to devote significant time and resources and to incur expenses in identifying and evaluating strategic alternatives for the company, which could have a material adverse effect on our business. A considerable portion of these expenses may be incurred regardless of whether a transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, potential strategic transactions that require stockholder approval may not be approved by our stockholders or, if required, a counterparty's stockholders. Further, any strategic transaction that is completed ultimately may not deliver the benefits we expect or enhance stockholder value.

Pursuing or consummating any strategic transaction may disrupt our management or business, require us to incur non-recurring or other charges, increase our near- and long-term expenditures, and may pose significant integration challenges, which could adversely affect our operations and financial results. For example, pursuing or consummating these transactions may entail numerous operational and financial risks, including:

- the inability to retain our key employees or our other service providers;
- increased volatility of our stock price;
- higher than anticipated transaction or integration costs;
- exposure to unknown liabilities;
- write downs of assets or goodwill or impairment charges;
- increased amortization expenses; and
- the possibility of future litigation.

Accordingly, there can be no assurance that we will undertake or successfully complete any strategic transactions of the nature described above and any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and prospects.

In the event that we do not successfully identify a viable strategic alternative, or consummate such a transaction, or if we are unable to raise sufficient capital to fund our operations, our board of directors may determine to pursue a liquidation and dissolution or other wind down of our business. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify strategic alternatives for our business will result in a successfully consummated transaction. If we are unable to identify a viable strategic alternative or if such a transaction is not completed in a timely manner, or if we are unable to raise sufficient capital to fund our operations, our board of directors may determine to pursue a liquidation and dissolution or other wind down of our business. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic options.

In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our business, we would be required under Delaware law (in addition to paying the costs of the liquidation) to pay our outstanding obligations, as well as to make reasonable provisions for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the satisfaction of such obligations. In addition, we may be subject to litigation or other claims related to a liquidation and dissolution of our business. If a liquidation and dissolution are pursued, our board of directors, in consultation with its legal and financial advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve.

Accordingly, holders of our securities may suffer a total loss of their investment.

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that product candidates will fail to prove effective, gain regulatory approval or become commercially viable. We have one product, Ebvallo, which is approved in the EEA, the UK and Switzerland and have generated limited revenues from commercialization, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have incurred significant operating losses in every annual reporting period since our inception. For the year ended December 31, 2024, we reported a net loss of \$85.4 million.

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

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

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

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

We have earned limited commercialization revenues to date. We may never achieve profitability.

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

- successfully complete development activities, including the necessary clinical studies with positive results;
- complete and submit regulatory submissions to the FDA, EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- develop manufacturing and distribution processes for our novel T-cell immunotherapy product candidates;
- develop commercial quantities of our products, including at acceptable cost levels;
- establish and maintain adequate supply of our products, including cell lines with sufficient breadth to treat patients;
- establish and maintain manufacturing and commercialization relationships with reliable third parties;
- qualify our CMOs' manufacturing facilities such that we can maintain the supply of our products by ensuring adequate manufacturing of bulk drug substances and drug products in a manner that is compliant with global legal and regulatory requirements;
- achieve market acceptance of and pricing and reimbursement for our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property and regulatory protections portfolio; and
- find suitable commercialization partners who can obtain coverage and adequate reimbursement from third parties, including government payors, set commercially viable prices, market, sell and distribute our approved products.

Our revenues from Ebvallo or any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and the terms and conditions of our commercialization agreement with our partner for that territory. We do not retain any meaningful milestones or royalty payments from Pierre Fabre for Ebvallo in the Initial Territory until the applicable royalty cap under the HCRx Agreement is met, which could take many years, if at all. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice, treatment guidelines or a reduction in the incidence of the addressable disease, our partners may not successfully commercialize our products, even if approved. The timing and amount of any milestone and royalty payments we may receive from our partners, as well as the commercial success of our products will depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of our products by our partners. As a result, even if we generate product revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require substantial near-term financing to continue operations, 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, impair our exploration of strategic alternatives, or require us to pursue a liquidation and dissolution or other wind down of our business.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and manufacturing of our T-cell immunotherapy product candidates. 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 do not believe that our existing cash, cash equivalents and short-term investments are sufficient to fund our operations and ongoing activities in the near term, and believe that approximately \$15 million in additional financing is necessary to fund our ongoing activities required to achieve BLA approval for tab-cel. Such estimates are based on assumptions and plans that are subject to change and such changes could materially impact our expected cash runway. These assumptions include the receipt of future payments that are dependent upon the successful transition of substantially all activities relating to tab-cel to Pierre Fabre by the end of the first quarter of 2025, as well as the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time. Any delay in these transition and other activities will create additional expenses and cash needs for us.

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

As of December 31, 2024, we had total cash, cash equivalents and short-term investments of \$42.5 million. Our existing cash, cash equivalents and short-term investments as of December 31, 2024 will not be sufficient to fund our planned operations for at least the next twelve months from the date of issuance of these financial statements. These conditions raise substantial doubt about our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements.

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

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

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

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

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

In August 2022, we reduced our workforce by approximately 20% across all areas of our company, including members of management. In November 2023, we further reduced our workforce by approximately 30%. In January 2024, we announced another reduction of our workforce by approximately 25%. In January 2025, we announced another reduction of our workforce by approximately 50%. In March 2025, we further reduced our workforce by approximately 50%, retaining approximately 35 employees essential to executing on our strategic priorities. The reductions in force reflect a prioritization around key research and development programs and the reduction of our expense profile. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from restructuring, our operating results and financial condition would be adversely affected. We also cannot be certain that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our cost savings plan may be disruptive to our operations, which could affect our ability to generate product revenue. In addition, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, and manufacturing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our product candidates in the future, including tab-cel, if approved.

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

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

Risks Related to the Development of Our Product and Product Candidates

We have one approved product, Ebvallo, which is currently approved in the European Economic Area (EEA), the UK and Switzerland. In March 2025, we announced our decision to pause the development of our allogeneic CAR T programs and discontinue all CAR T development operations. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop, manufacture and commercialize our product or product candidates or experience significant delays in doing so, our business may be materially harmed.

We have one approved product, Ebvallo, which is currently approved in the EEA, the UK and Switzerland. 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 and manufacture, and our partners' eventual commercialization of our product and product candidates.

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

- completion of preclinical and clinical studies with positive results, including demonstrating the stability, safety, purity, and potency of our product candidates to the satisfaction of the FDA or other regulatory agencies;
- receipt of regulatory approvals from applicable authorities, including required authorizations for clinical trials and marketing authorizations;
- protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing or making successful arrangements with third party manufacturers and commercialization partners;
- qualifying our and our CMOs' manufacturing facilities for clinical and commercial manufacturing purposes;
- developing manufacturing and distribution processes for our novel T-cell product candidates and next-generation CAR T programs;
- contracting with third parties for the manufacture of our product candidates at an acceptable cost;
- contracting with third parties for commercialization of our products on terms favorable to us, if approved by applicable regulatory authorities;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- our partners' ability to obtain and maintain coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other therapies;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop our products and technology.

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

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

Our business could be adversely affected by health epidemics and pandemics which may present substantial public health and economic challenges around the world.

Our clinical trials may also be affected by health epidemics and pandemics due to interruptions to clinical trial site data monitoring and the collection, processing, and analyses of efficacy, safety, and translational data. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to health epidemics and pandemics, may be adversely impacted.

Our future success is dependent on the marketing authorization of our product candidates.

We only have one product, Ebvallo, that has gained marketing authorization, with approval currently in the EEA, the UK, and Switzerland. Our prioritized clinical-stage product candidates include tab-cel (tabelecleucel) 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 marketing authorization for the product candidates from the FDA; similarly, neither we nor our partners can commercialize product candidates outside of the U.S. without obtaining marketing authorization 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 MAA for Ebvallo as a monotherapy treatment for patients with EBV+ PTLD who have received at least one prior therapy under "exceptional circumstances," which is a pathway under which marketing authorization is granted when "comprehensive data cannot be obtained even after authorization." The MHRA and Swissmedic approved the marketing application for Ebvallo leveraging the EMA assessment. Under the exceptional circumstances marketing authorization, our commercial partner, Pierre Fabre, is subject to ongoing post-marketing obligations to continue confirmation of the benefits of Ebvallo, and if any of our other product candidates are approved under this pathway, we or our future commercial partners will be subject to this obligation. Continuation of the Ebvallo marketing authorization is subject to annual re-assessment. The annual re-assessment will determine whether the Ebvallo marketing authorization should be maintained, changed, or suspended, based on Pierre Fabre's fulfillment of post-marketing obligations and the risk/benefit profile of Ebvallo. If we, or our commercial partners, do not satisfy the ongoing post-marketing obligations or the risk/benefit profile of Ebvallo is determined not to be acceptable based on new clinical or post-marketing data, the EC, MHRA, or Swissmedic may change or suspend the marketing approval for Ebvallo. We have not obtained regulatory approval for any other product candidate, and it is possible Ebvallo (tabelecleucel) may not be approved in any other country other than those in which approval has been obtained and also possible that none of our other product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical studies;
- failure to demonstrate positive benefit/risk profile of the product candidate for its proposed indication;
- failure to demonstrate the stability, safety, purity and potency of the product candidate;
- failure of clinical sites to conduct the study in accordance with applicable regulatory requirements;
- failure of clinical studies to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical studies;
- the insufficiency of data collected from clinical studies of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- inability to reach agreement with the FDA or comparable foreign regulatory authorities on the methodologies for, and assessment of, comparability of different versions of product candidates used in non-pivotal studies, pivotal studies and for intended commercial use;
- failure to obtain approval of our manufacturing processes or facilities of third party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes or inconsistencies in the requested or required methodologies, statistical analyses, specification criteria or regulatory submission requirements for a product candidate, including changes to, or inconsistencies with, applicable industry practice or precedent; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval or in positions, guidance or feedback communicated by the FDA or comparable foreign regulatory authorities that have a negative impact on the potential approval of a product candidate.

The FDA or a comparable foreign regulatory authority may require information beyond what we plan to provide in or expect to be required for a marketing application, including additional CMC information, preclinical or clinical data to support approval. These requirements may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. For example, at a Type B meeting in February 2022, we were not able to align with the FDA on comparability between tab-cel product versions used in the pivotal ALLELE study and the intended commercial product. The FDA initially recommended we conduct a new clinical trial with the commercial product to address the lack of alignment on comparability and to gain additional clinical experience with the intended commercial product. Throughout 2023, we held a number of meetings with the FDA on clinical

and CMC aspects for a potential BLA submission for tab-cel. Ultimately, we reached agreement with the FDA on the comparability of tab-cel product manufactured using a different process version with the intended commercial product and subsequently held a pre-BLA meeting with the FDA that supported our plan to submit the tab-cel BLA in the second quarter of 2024. The BLA was submitted in May 2024, and the FDA accepted the BLA submission in July 2024 and granted priority review with a Prescription Drug User Fee Act target action date of January 15, 2025. Although the FDA designated tabeclucel as a breakthrough therapy, a breakthrough designation (BTD) status is not considered in the FDA's decision to approve or not approve a product candidate. Designation as a breakthrough therapy is at the discretion of the FDA, and receipt of a BTD designation may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the conditions for qualification and rescind the BTD designation or decide that the time period for FDA review or approval will not be shortened. Furthermore, our CMOs for tab-cel will undergo pre-approval inspection in connection with our tab-cel BLA, and we cannot be certain that we will be able to adequately support them through such inspection nor that they will successfully pass any such inspection. For example, we received the Response Letter from the FDA in January 2025 relating solely to observations during pre-approval inspection of a third-party manufacturing facility in connection with our tab-cel BLA. In addition, in January 2025, the FDA placed a clinical hold on Atara's active Investigational New Drug (IND) applications. These INDs include the tab-cel program as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLTD) and ATA3219 for the treatment of non-Hodgkin's lymphoma and systemic lupus erythematosus. Some clinical sites that participated in tabeclucel studies will also undergo inspection, and the FDA may also choose to inspect us as the sponsor of these studies. The FDA ultimately may not approve the BLA for any of the reasons named above or other reasons. If the FDA does not approve the BLA, this could result in a considerable delay to a subsequent BLA submission or could lead us not to pursue a BLA submission at all. For example, the FDA may not approve the BLA based on the data provided, including a concern that the current clinical dataset is insufficient. In this case, the conduct of an additional clinical trial or trials in the lead indication or completing the ongoing ALLELE study may be necessary to support a BLA approval for tab-cel. Conducting an additional clinical trial, if required, may prove too difficult or too expensive, and the process of designing a new clinical trial, enrolling enough patients, and completing treatment and data collection under the protocol could take a significant amount of time, effort, and resources. Even if we complete the clinical trial, the study may not meet its prespecified endpoints, and even if it does, the FDA may still disagree that the clinical trial is sufficient to support submission and approval of a BLA for tab-cel, or may consider that the data, while adequate for BLA approval, can support only a more limited indication than that for which we initially applied.

Our development activities and/or commercialization planning with our partners could be harmed or delayed by governmental or regulatory delays due to a variety of factors. These factors include limitations on the availability of governmental and regulatory agency personnel to review regulatory filings or engage with us (caused by global health concerns or otherwise); 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 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.

If we do obtain approval for a product candidate marketing application, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In addition, the clinical study requirements of the FDA, EMA, MHRA, Swissmedic, 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, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EC and FDA of autologous CAR T therapies, such as Novartis' Kymriah[®] and Gilead's Yescarta[®], may not be indicative of what these regulators require for approval of our therapies. If an adverse safety issue or other adverse finding occurs in one or more of our clinical trials, including those that could result in a clinical hold, such events could adversely affect our other clinical trials of the same or related product candidates. Moreover, our product candidates may not perform successfully in clinical studies or may be associated with adverse events that distinguish them from those that have previously been approved, such as approved autologous CAR T therapies. For instance, exposure to allogeneic product candidates may result in adverse events not experienced with autologous products. Even if a product candidate is approved by the FDA and comparable foreign regulatory authorities, the approval might contain significant limitations related to use for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate

revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn in a region or country by the respective regulatory agency.

Our T-cell immunotherapy product and product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or our inability to achieve regulatory approval, commercialize or secure payor coverage of our product candidates.

Our future success is dependent on the successful development and commercialization of T-cell immunotherapies 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 but not limited to:

- 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;
- 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 or that processes will 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.

Furthermore, regulatory agencies may also modify or enhance trial requirements which may affect enrollment. For example, in August 2023, the FDA published a guidance document entitled, Informed Consent, Guidance for IRBs, Clinical Investigators, and

Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial and could cause a significant setback to an applicable program.

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

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

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

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. Adverse differences between preliminary or interim data and final data could impact the regulatory approval of, and/or 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. For example, in January 2025, the FDA placed a clinical hold on our INDs for tab-cel as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre-approval inspection of a third party manufacturing facility referenced in a Response Letter we received in January 2025. Our ATA3219 product candidate is manufactured at a separate, fully compliant GMP-certified facility, the starting material used in its production are affected by the compliance issues at the same third-party facility referenced in the Response Letter. In addition, the new EU Clinical Trials Regulation (EU) No 536/2014 (CTR) has amended the system of approval for clinical trials in the EU and has established a new clinical trials portal and database, called the Clinical Trials Information System (CTIS), for the submission and authorization of clinical trial applications. Clinical studies may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

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

- data that demonstrate an unacceptable benefit/risk profile, including a lack of efficacy, unforeseen safety issues or adverse side effects
- difficulties in manufacturing or obtaining from third parties sufficient quantities of clinical product and/or inability to supply a 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;
- non-compliance with CTIS processes under the new EU Clinical Trial Regulation, including with the CTIS transparency rules, which became applicable on June 18, 2024 and which will require adapting business processes of clinical trial sponsors; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical study.

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

- the size and nature of the patient population;
- the possibility that the rare diseases that many of our product candidates address are under-diagnosed;
- changing medical practice patterns or guidelines related to the diseases or conditions we are investigating;
- the severity of the disease under investigation;
- our ability to open clinical study sites;
- the proximity of subjects to clinical sites;
- the patient referral practices of physicians;
- the design and eligibility criteria of the clinical study;
- ability to obtain and maintain patient consents;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical studies;
- our or our partner's ability to manufacture the requisite materials for a study;
- risk that we do not have appropriately matched HLA cell lines;
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the diseases or conditions we are investigating; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic.

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

We rely on CROs, other vendors and clinical study sites to ensure the proper and timely conduct of our clinical studies, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Reliance on CROs entails risks to which we would not be subject if we conducted our clinical studies ourselves, including reliance on the CRO for

clinical site initiation and monitoring, the possibility that the CRO does not maintain the financial resources to meet its obligations under our agreements, the possibility of breach of these agreements by the CRO because of factors beyond our control, including a failure to properly perform their obligations under these agreements, and the possibility of termination or non-renewal of the agreements by the CROs, based on their own business priorities, at a time that is costly or damaging to us. For example, the CRL MSA expired on August 31, 2024 and we are in negotiations to wind-down our activities at CRL. We are exploring other options for the manufacture of our product and product candidates. There can be no assurance that we will be able to find a new CMO or enter into a new commercial drug product supply agreement with a new CMO on terms favorable or acceptable to us or at all. Any delays in entering into a new commercial manufacturing agreement could delay the development and commercialization of our product and product candidates, if approved.

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, or our third party vendors', 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 government-sponsored databases, such as ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

- we may be forced to suspend marketing of that product;
- regulatory authorities, IRBs, or other clinical trial oversight bodies may place a hold on any ongoing clinical trials;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients;
- our products may be seized, or we may be required to recall our products;
- our products may become less competitive in the marketplace; and
- our reputation may suffer.

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

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

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

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

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

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

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA, the EMA, and the MHRA from approving another marketing application for the same biologic for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in the EU and the UK. The EU and UK exclusivity periods can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. These periods may be reduced in the EU based on a new applicable legal framework, currently under review by the European Parliament and Council. Orphan drug exclusivity may be lost if the FDA, EMA or MHRA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In the U.S., the FDA may still approve a later marketing application blocked by an ongoing period of orphan drug exclusivity in limited circumstances such as a demonstration of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was approved. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve or license other drugs or biological products that have a different active ingredient for use in treating the same indication or disease.

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

We have obtained BTD for tab-cel in the U.S. for treatment of patients with EBV+ PTLD who have failed rituximab, however this designation may not lead to faster development or regulatory review and does not increase our likelihood of success. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the study can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for other expedited review programs, such as priority review. Even though the FDA may grant priority review of a marketing application for a product granted BTD, BTD status is not considered in the FDA's decision to approve or not approve a product candidate.

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

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 BTM 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 BTM 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 BTM for products that no longer meet the requirements for that designation.

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

We may seek fast track designation for one or more of our future product candidates. If a drug or biological product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA fast track designation for a particular indication. We may seek fast track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates, even if such a designation has been granted to similar products. Marketing applications submitted by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing licensure by the FDA.

The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways and receiving a fast track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw fast track designation at any time, including if it believes that the designation is no longer supported by data from our clinical development program.

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

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

The proposed revision of the European legislation on pharmaceuticals, changes in governmental administration or changes in leadership at relevant agencies could lead to uncertainties over the regulatory framework that will be applicable to medicinal products in the EU and US, including orphan medicinal products.

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

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

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

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

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

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

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

Changes to 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+ PTLTD as set forth in the National Comprehensive Cancer Network Guidelines, future guidelines from governmental agencies, professional societies, practice management groups, private health/science foundations and other organizations could lead to decreased ability to develop our product candidates, or decreased use of our products once approved by applicable regulatory authorities.

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

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

Risks Related to Manufacturing

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

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

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

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

The process of manufacturing cellular therapies is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product and product candidates could result in reduced production yields, impact to key product quality attributes, and other supply disruptions. Product defects can also occur unexpectedly. If microbial, viral or other contamination is discovered in reagents or in our product or product candidates or in the manufacturing facilities in which our product and product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. For example, we have been informed by a CMO of mold and other contamination in certain manufacturing suites related to the manufacture of finished Ebvallo and tab-cel product and intermediates at the CMO's facility. We have had to, and may in the future need to, pause certain manufacturing activity at this CMO. We continue to work with the CMO to investigate and remediate contamination issues but can make no assurance regarding such remediation efforts. 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, which can be weeks. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. Viral contaminants may also arise in recombinant viral reagent production systems used to manufacture viral reagents used to manufacture product and product candidates. These types of contamination could result in delays in the manufacture of products which could result in delays in the development of our product candidates. Contamination could also increase the risk of adverse side effects. Furthermore, our allogeneic products ultimately consist of many individual cell intermediate or cell product lots, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell product lot for therapeutic use in a patient requires close coordination between clinical operations, supply chain and quality assurance personnel.

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

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

The research and development and process and analytical development labs within ARC and our facility in Aurora, Colorado, currently support our mid/late development activities. Product-specific qualification to support clinical development and commercial production qualification activities are ongoing for product candidates at our CMOs' facilities. If the appropriate regulatory approvals for manufacturing product candidates at our CMOs' facilities are delayed, we may not be able to manufacture sufficient quantities of our product candidates, which would negatively impact commercial supply, limit our development activities and limit 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 partners', 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 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. For example, in January 2025, we received the Response Letter from the FDA relating solely to observations during pre-approval inspection of a third-party manufacturing facility in connection with our tab-cel BLA. The FDA also placed a clinical hold on our INDs for tab-cel as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre-approval inspection of a third party manufacturing facility referenced in the Response Letter we received in January 2025. Although our ATA3219 product candidate is manufactured at a separate, fully compliant GMP-certified facility, the starting materials used in its production are affected by the compliance issues at the same third-party facility referenced in the Response Letter. 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 and commercial product. 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. For example, in January 2025, we received the Response Letter from the FDA relating solely to observations during pre-approval inspection of a third-party manufacturing facility in connection with our tab-cel BLA. The FDA also placed a clinical hold on our INDs for tab-cel as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre-approval inspection of a third party manufacturing facility referenced in the Response Letter we received in January 2025.

To meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of tab-cel, product candidates resulting from our next-generation CAR T programs or any other product candidates, we will need to transition the manufacturing of these materials to a CMO. Regardless of where production occurs, we will need to develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability and/or non-inferiority 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 have been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced with that generated by us or our CMOs.

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

We still may need to identify additional CMOs for continued production of supply for some of our product and product candidates. Given the nature of our manufacturing processes, the number of CMOs who possess the requisite skill and capability to manufacture our T-cell immunotherapy product candidates, and the critical intermediates or reagents used to manufacture such products, are limited. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them.

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

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

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product and product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we or our partners may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, the possibility that the third party does not devote sufficient time or resources to our product candidates or any products we or our partners may eventually commercialize based on its own business priorities, the possibility that the third party is acquired by another party and changes its business priorities, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. For example, the CRL MSA expired on August 31, 2024 and we are in negotiations to wind-down our activities at CRL. We are exploring other options for the manufacture of our product and product candidates, there can be no assurance that we will be able to find a new CMO or enter into a new commercial drug product supply agreement with a new CMO on terms favorable or acceptable to us or at all. Any delays in entering into a new commercial manufacturing agreement could delay the development and commercialization of our product and product candidates, if approved. 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 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 of 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.

In January 2025, we received the Response Letter from the FDA relating solely to observations during pre-approval inspection of a third-party manufacturing facility in connection with our tab-cel BLA. The FDA also placed a clinical hold on our INDs for tab-cel, as well as our product candidate ATA3219. The clinical hold is directly linked to inadequately addressed GMP compliance issues identified during the pre-approval inspection of a third party manufacturing facility referenced in the Response Letter. Although our ATA3219 product candidate is manufactured at a separate, fully compliant GMP-certified facility, the starting materials used in its production are affected by the compliance issues at the same third-party facility referenced in the Response Letter.

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

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

depend on, among other things, the efforts, allocation of resources, negotiation of pricing and reimbursement and successful commercialization of tab-cel by Pierre Fabre.

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

Furthermore, we are responsible for manufacturing and supplying tab-cel to Pierre Fabre for commercialization in the Territory at cost plus a margin until the transfer of manufacturing responsibility to Pierre Fabre. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab-cel in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of i) the date on which all activities relating to the transfer of tab-cel manufacturing, pursuant to the A&R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, throughout the remainder of the term of the A&R Commercialization Agreement. Pierre Fabre and we are to use commercially reasonable efforts to achieve this prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the first BLA. We are in active discussions with Pierre Fabre on accelerating the progressive transfer of all operational activities related to tab-cel, except the BLA sponsorship, to be completed as early as the end of the first quarter of 2025, as well as assumption by Pierre Fabre of certain costs related to the remediation of the third party manufacturing facility to address the FDA's requests in order to lift the clinical hold and to support resubmission of the BLA for tab-cel. As part of these discussions, we expect to agree to reduce the amount of certain future potential regulatory and commercial milestone payments relating to tab-cel in the Additional Territory. Any delays in completing the manufacturing transfer to Pierre Fabre will increase our costs in order to meet our supply obligations and adversely impact our ability to develop our product candidates, and any reduction in amounts of future potential regulatory or commercial milestone payments may impact our future cash flows.

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

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

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

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

for development or commercialization, curtail or abandon that development or commercialization, or undertake and fund the development and commercialization of the relevant product. If we seek a new partner but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of products ourselves, we would have to explore other strategic options, including curtailing or abandoning that development or commercialization, which could harm our business.

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 and 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 being issued 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 products 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 still 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 products 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.

Additionally, 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 with claims directed to our product and product candidates or methods of using or making the product and 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 claims in 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 foreign 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, product 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 reasonable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us.

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

Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product, 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 products and product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the U.S. may be less extensive than those in the U.S. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the U.S. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the U.S., or from selling or importing infringing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the U.S. These infringing products may compete with our product and product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

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

We hold rights under license agreements with our partners, including MSK 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. For example, we are in disagreement with MSK on whether we owe a portion of the upfront payments and milestones we received from Pierre Fabre under the A&R Commercialization Agreement to MSK under the terms of our license agreements with MSK. We have entered into evaluative non-binding mediation with MSK to potentially resolve this disagreement. There is no guarantee we will reach a favorable outcome in the mediation or on this matter and we may owe a portion of future milestones we receive from Pierre Fabre to MSK. 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 developing a clearly differentiated product and attaining significant market acceptance of our product and product candidates, if approved, among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics.

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

- the efficacy and safety of the product candidates as demonstrated in clinical studies;
- the clinical indications and patient populations for which the product candidate is approved;
- the inclusion into clinical treatment guidelines;
- acceptance by physicians and patients of the drug as a safe and effective treatment;
- the administrative and logistical burden of treating patients;
- the differentiation profile versus other approved therapies at the time of commercialization;
- the ability to identify in a timely manner the appropriate patients who will benefit from specific therapy;
- the consideration of novel cellular therapies by physicians, hospitals and third party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

- the geography and timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our product and product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from, and our commercialization partners' ability to negotiate pricing with, third-party payors and government authorities;
- the limited healthcare resources to accommodate CAR T therapies;
- relative convenience and ease of administration;
- the ability to achieve a pricing and reimbursement recommendation or commercial agreement with national payors; and
- the effectiveness of our commercialization partners' sales and marketing efforts.

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

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

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

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

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

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product and product candidates for which we obtain regulatory approval. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act (ACA), was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. As of January 1, 2024, manufacturers' Medicaid Drug Rebate Program rebate liability is no longer capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by the U.S. Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013. As a result of the COVID-19 pandemic, this reduction was temporarily suspended from May 1, 2020 through March 31, 2022, with subsequent reductions to 1% from April 1, 2022 through June 30, 2022. The 2% reduction was then reinstated and has been in effect since July 1, 2022, and will remain in effect through the first eight months in which the FY 2032 sequestration order is in effect. In January 2013, the American Taxpayer Relief Act of 2012 was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product and product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the U.S. or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product and product candidates, if any, may be. In the U.S., the EU and other potentially significant markets for our product and product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. In the U.S., there have been several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Consolidated Appropriations Act of 2021 included several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of Health and Human Services, Labor, and the Treasury. Additionally, the IRA allows Medicare to: beginning in 2026, establish a “maximum fair price” for certain pharmaceutical and biological products covered under Medicare Parts B and D; beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation; and beginning in 2025 impose new discount obligations on pharmaceutical and biological manufacturers for products covered under Medicare Part D. CMS continues to take steps to implement the IRA, including, most notably: releasing the negotiated maximum prices, which will be effective in 2026, for the first ten drugs that were subject to the IRA’s negotiation process, releasing quarterly lists of Medicare Part B products that are subject to adjusted coinsurance rates based on the inflationary rebate provisions of the IRA, and announcing a list of fifteen additional drugs that will be subject to price negotiations during 2025. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U.S. Department of Health and Human Services, the Secretary of the U.S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA’s drug price negotiation provisions.

There have also been administrative developments in the U.S. related to drug pricing. For example, on June 27, 2023, the Center for Medicare Innovation at CMS announced a new model, the Enhancing Oncology Model, that is designed to make high-quality cancer care more affordable to both patients and Medicare. Additionally, on February 14, 2023, the Department of Health and Human Services issued a report which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a “high-value drug list” setting the maximum out-of-pocket costs for certain common generic drugs at \$2 per month per drug; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements for certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments.

Other recent administrative actions may affect our upcoming government pricing responsibilities stemming from our anticipated participation in government pricing programs. For example, in September 2024, CMS published a final rule that included significant revisions to certain Medicaid Drug Rebate Program provisions, including, but not limited to: (i) new definitions for key terms under the Medicaid Drug Rebate Program, such as “covered outpatient drug” and “market date”; (ii) revised processes for identifying drug misclassifications, as well as additional penalties that can be imposed against manufacturers in connection with such misclassifications; and (iii) a new 12-quarter time limit for manufacturers to initiate disputes, hearing requests, and audits for state-invoiced rebate amounts. In addition, there are pending legal and legislative developments relating to the 340B drug pricing program, including ongoing litigation challenging federal enforcement actions against manufacturers and recently introduced and enacted state legislation. In March 2024, the US Court of Appeals for the Eighth Circuit upheld the Arkansas law prohibiting drug makers for restricting 340B drug discounts for providers using contract pharmacies. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry.

The results of the 2024 Presidential and Congressional elections, and potential subsequent developments further increase the uncertainty related to the healthcare regulatory environment, particularly given the Trump Administration's stated commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS and CMS. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) “must exercise their independent judgment” and “may not defer to an agency interpretation of the law simply because a statute is ambiguous.” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by CMS and other agencies with significant oversight of the healthcare industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies may be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts that are difficult to predict but could have a material adverse effect on our business and financial condition. For example, certain of these changes could impose additional limitations on the rates we will be

able to charge for our future products or the amounts of reimbursement available for our future products from governmental agencies or third-party payors.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be “high-cost”. Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the EU will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, other insurers, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

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

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

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

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

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product and product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, patient convenient, have fewer side effects or are less expensive than any products that we may develop, and if our product cannot be administered in a treatment setting proximate to the patient (e.g., community practices). 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 relapse and/or refractory of EBV+ PTLD, and there are no EC-approved products for this indication except for Ebvallo. However, we are aware some marketed products and therapies are used per global physician treatment guidelines in the US and the EU in the treatment of EBV+ PTLD by some healthcare professionals and institutions, such as rituximab and combination chemotherapy regimens.

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

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

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

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

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

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

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

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

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

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

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

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

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

As of December 31, 2024, we had 153 employees. We may encounter difficulties in managing the size of our operations to support our continuing development activities and the commercialization of our product and potential commercialization of our product candidates by our partners. As our development and commercialization plans and strategies continue to evolve, or as a result of any future acquisitions, we must continue to improve our managerial, operational, financial and other procedures and processes to manage the size of our 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 clinical studies effectively;
- managing CMC operations and our external manufacturing partners effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including the additional personnel needed to support continued development and of our product candidates;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

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

Risks Related to Ownership of Our Common Stock

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

Our stock price has fluctuated in the past and can be expected to be volatile in the future. On June 20, 2024, we effected a 1-for-25 reverse stock split of our common stock, which contributed to the fluctuation in our stock price. From January 1, 2023 through December 31, 2024, the reported sale price of our common stock has fluctuated between \$4.97 and \$141.00 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 the general volatility of the biopharmaceutical market, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, or other employee of the Company to us or our stockholders, (iii) any action asserting a claim against us or any of our directors, officers, or other employees arising pursuant to any provision of the DGCL or our Certificate of Incorporation or Bylaws (as either may be amended from time to time), (iv) any action asserting a claim against us governed by the internal affairs doctrine, or (v) any other action asserting an "internal corporate claim," as defined under Section 115 of the DGCL. The forgoing provisions do not apply to any claims arising under the Securities Act and, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act.

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

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

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

If we choose to rely on any of these reporting and disclosure exemptions, the information we provide stockholders will be different than the information that is available with respect to many other public companies. Moreover, if some investors find our common stock less attractive as a result of any choices to reduce future disclosure or not having an independent review and attestation of our internal control over financial reporting, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

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

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

General Risk Factors

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

We are highly dependent upon our executive officers and other key employees and the loss of the services of any of our executive officers or other key employees, including scientific, technical or management personnel, could impede the achievement of our corporate objectives. In August 2022, we announced a reduction of our workforce by approximately 20% across all areas of our company, including members of management. In November 2023, we implemented a further reduction of our workforce by approximately 30%, and in January 2024, we conducted an additional reduction of our workforce by approximately 25%, including a member of management. In September 2024, Pascal Touchon, our President and Chief Executive Officer stepped down from his position and was appointed Chairperson of our board of directors, and AnhCo “Cokey” Nguyen, our Chief Scientific and Technical Officer, was appointed as our President and Chief Executive Officer. 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. In addition, we may not be able to effectively transition members of our management, including transitioning Dr. Nguyen into the position of President and Chief Executive Officer.

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

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

Healthcare providers, including physicians, and third party payors will play a primary role in the recommendation and prescription of our product and any product candidates for which we obtain regulatory approval. Our current and future arrangements with third party payors and customers may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are and will be applicable to our business. If we obtain FDA approval of any of our product candidates and our partners begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs, distribution agreements, discounting, commission compensation, certain patient support offerings, and other business arrangements generally. In addition, the approval and commercialization of our product and any of our product candidates outside the United States will also likely subject us to foreign equivalents of such healthcare laws, among other foreign laws. See Part I, Item 1, “Government Regulation and Product Approval – U.S. Health Care Laws” for additional details on applicable federal and state healthcare laws and regulations that may affect our business operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the EU GDPR also prohibits the transfer of personal information from the EEA to countries that the European Commission does not recognize as having an “adequate” level of data protection unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information (e.g., EU Standard Contractual Clauses or EU SCCs). Data protection laws in the UK (as discussed below) and Switzerland impose similar restrictions. There is also a requirement in certain cases for companies to carry out a transfer impact assessment (TIA) which, among other things, assess laws governing access to personal information in the recipient country and considers whether supplementary measures that provide privacy protections additional to those under the EU SCCs will need to be implemented to ensure an “essentially equivalent” level of data protection to that afforded in the EU.

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

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

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

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

Cybersecurity requirements are laid down in various laws in the EU and the UK, the key ones being: (i) the GDPR (as discussed above), which requires controllers and processors to implement appropriate technical and organizational measures to safeguard personal data to a level of security appropriate to the data protection risk; (ii) the UK Network and Information Systems Regulation 2018 (NIS Regulations), and (iii) EU Network and Information Systems Security 2 Directive (NIS2). Under the NIS2, stringent cybersecurity and incident reporting requirements are imposed on “essential” and “important” entities, including, for example, entities carrying out research and development activities of medicinal. NIS2 states that any maximum fine which national implementing law provides for should at least be set at €10 million or 2% of total worldwide turnover, whichever is higher, where essential entities are concerned. Other sanctions may include (i) a temporary suspension to provide services in the EU (by suspending relevant authorizations/certifications); (ii) an order to make public certain elements of the infringement and/or inform customers; and (iii) injunctions to immediately cease infringing conduct. Importantly, NIS2 also provides that senior members of staff can be held personally liable, and face administrative fines or be temporarily suspended from exercising managerial functions at the legal representative or chief executive officer level.

Other countries outside of Europe and the UK continue to enact or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and

operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the EU GDPR and the UK GDPR.

Regulation of privacy, data protection, and data security has also become more stringent in the United States. HIPAA imposes requirements to protect the privacy and security of protected health information (PHI) and to provide notification in the event of a breach of PHI. Violations of HIPAA are punishable by civil money penalties and, in some cases, criminal penalties and imprisonment. HHS' Office for Civil Rights (OCR), which is responsible for enforcing HIPAA, also may enter into resolution agreements requiring the payment of a civil money penalty and/or the establishment of a corrective action plan to address violations of HIPAA. Pursuant to HIPAA, HHS has adopted privacy regulations, known as the privacy rule, to govern the use and disclosure of PHI (the Privacy Rule). HHS has also adopted data security regulations that require Covered Entities and Business Associates to implement administrative, physical and technical safeguards to protect the integrity, confidentiality and availability of PHI that is electronically created, received, maintained or transmitted (such as between us and our affiliated practices). While the vast majority of HIPAA obligations do not apply to pharmaceutical companies or clinical trial data, the requirements inform privacy and security practices across the industry and may impact interactions with health care providers.

Numerous state laws are also designed to address privacy and information security issues, including but not limited to state medical privacy laws, state laws protecting personal information, state data breach notification laws, state genetic privacy laws, human subjects research laws and federal and state consumer protection laws. For example, the CCPA, which took effect on January 1, 2020, give California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. The CCPA was substantially expanded on January 1, 2023, when the 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.

Regulation of privacy, data protection and data security has also become more stringent in the United States, with several new laws following the CCPA and being enacted at the state level, including several comprehensive privacy laws. While these new laws and proposals generally include exemptions for HIPAA-covered data and clinical trial data, they add layers of complexity to compliance in the U.S. market, and could increase our compliance costs and adversely affect our business. Multiple other states and the federal government are considering enacting similar legislation, demonstrating a strong trend towards more stringent state privacy, data protection and data security legislation in the U.S., which could increase our potential liability and adversely affect our business. Other states have passed or amended existing state privacy laws to impose enhanced privacy and cybersecurity obligations for consumer health data, such as, the Washington My Health My Data Act and Nevada's Consumer Health Data Privacy Law. For instance, Washington State's "My Health My Data Act" regulates "consumer health data" which is defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health."

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

Lawmakers and regulatory bodies at the federal level have been considering more detailed regulation regarding these subjects and the privacy and security of personal information. For example, the FTC published an advance notice of proposed rulemaking on "commercial surveillance" and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. The FTC's rulemaking may create change throughout the economy and broader data ecosystem. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information. The FTC finalized changes to the Health Breach Notification. Additionally, in 2021, the OCR has issued a Notice of Proposed Rulemaking, which proposed a number of changes to the HIPAA Privacy Rule, and in 2025, the OCR issued a Notice of Proposed Rulemaking which proposed a number of changes to HIPAA Security Rule.

Compliance with applicable U.S. and foreign privacy, data protection, and data security laws and regulations may result in government investigations or cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2024, we had significant U.S. federal and state NOLs due to prior period losses. Under the Tax Cuts and Jobs Act (the Tax Act), federal NOLs generated in tax years beginning on or after January 1, 2018 may be carried forward indefinitely, but the utilization of such federal NOLs is limited to 80% of current year taxable income. States vary in conformity to all or portions of the Tax Act. The Tax Act did not have a material impact to our financial statements.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), our ability to utilize these NOLs and other tax attributes, such as federal tax credits, in any taxable year may be limited if we have experienced an "ownership change". Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year testing period. Similar rules may apply under state tax laws. We performed a Section 382 analysis of transactions in our stock through December 31, 2024 and concluded that we have experienced ownership changes since inception that we believe under Section 382 of the Code will result in limitations on our ability to use certain pre-change NOLs and credits. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our financial statements could be limited and, in the case of NOLs generated before January 1, 2018 may expire unused. Any such material limitation or expiration of our NOLs may harm our future operating results by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes. Regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, may cause our existing tax attributes to expire, decrease in value or otherwise be unavailable to offset future income tax liabilities.

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

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

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) “must exercise their independent judgment” and “may not defer to an agency interpretation of the law simply because a statute is ambiguous.” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles. For example, the current U.S. presidential administration has committed to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have established policies and processes designed to assess, identify, and manage material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. We monitor our environments to identify cybersecurity threats, as well as assess our environments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

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

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

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

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

Governance

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

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

Information Officer, executes with the goal of ensuring timely identification and appropriate resolution of cybersecurity incidents. In addition, we validate compliance with our internal data security controls through the use of security monitoring tools.

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

Item 2. Properties

Our corporate headquarters are located in Thousand Oaks, California and consists of approximately 33,659 square feet of office space under a lease agreement that expires in February 2032. In February 2025, we moved our headquarters to Atara Research Center, our existing office, lab, and warehouse space at 1280 Rancho Conejo Blvd, Thousand Oaks, CA 91320 (ARC).

The initial 10.5-year term of the ARC lease commenced in August 2021. We have the option to extend this lease for two additional five-year periods after the initial term.

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

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

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

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

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

On March 3, 2025, 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.

Item 6. [Reserved]

Not Applicable.

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

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

Overview

Atara Biotherapeutics is a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune disease. Tab-cel (tabelecleucel), our lead program in Phase 3 clinical development in the U.S., has received marketing authorization approval (MAA) under the proprietary name Ebvallo™ for commercial sale in the European Economic Area (EEA) by the European Commission (EC), for commercial sale and use in the United Kingdom (UK) by the Medicines and Healthcare products Regulatory Agency (MHRA), and for commercial sale and use in Switzerland by Swissmedic. 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). Our strategic priority is:

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

In March 2025, we announced our decision to pause development of our allogeneic CAR T cell programs and to discontinue development operations for our CAR T programs, including all clinical trials evaluating ATA3219 and development operations for ATA3431. We expect to complete wind-down activities for the CAR T programs by the end of the first quarter of 2025. We have also stopped development on ATA188, an allogeneic T-cell immunotherapy targeting multiple sclerosis (MS).

Our T-cell immunotherapy platform is potentially applicable to a broad array of targets and diseases. Our off-the-shelf, allogeneic T-cell platform allows for rapid delivery of a T-cell immunotherapy product manufactured in advance of patient need and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients. This differs from autologous treatments, in which each patient's own cells must be extracted, genetically modified outside the body and then delivered back to the patient, requiring a complex logistics network. We select the appropriate set of cells for use based on a patient's unique immune profile. One of our contract manufacturing organizations (CMOs) has completed commercial production qualification activities for tab-cel commercialization in the EEA and is in the process of completing commercial production qualification activities in the US. Another of our CMOs is currently in the process of completing commercial production qualification activities for tab-cel in the EEA. We continue to manufacture inventory according to Pierre Fabre's commercial product supply strategy.

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

On October 31, 2023, we entered into an amended and restated Pierre Fabre Commercialization Agreement (A&R Commercialization Agreement), pursuant to which we expanded Pierre Fabre's exclusive rights to research, develop, manufacture, commercialize and distribute tab-cel (Ebvallo) to include all other countries in the world (Additional Territory) in addition to the Initial Territory (together, the Territory), subject to our performance of certain obligations as described below. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of \$20.0 million for the expanded exclusive license grant, for which the cash was received in January 2024. In March 2024, we met the contractual right to receive \$20.0 million in milestone payments upon achieving a regulatory milestone, for which the cash was received in April 2024. In July 2024, we met the contractual right to receive an additional \$20.0 million in milestone payments upon achieving acceptance of our biologics license application (BLA) for tab-cel by the United States Food and Drug Administration (FDA) and we received the cash in August 2024. We will also be entitled to receive an aggregate of up to \$580.0 million in additional milestone payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory including up to \$60.0 million in potential regulatory milestones in connection with the approval by the FDA of a BLA for tab-cel. We are in active discussions with Pierre Fabre on accelerating the transfer of all operational activities related to tab-cel, except the BLA sponsorship, to be completed as early as the end of the first quarter of 2025, as well as assumption by Pierre Fabre of certain costs related to the remediation of the third party manufacturing facility to address the FDA's requests in order to lift the clinical hold and to support resubmission of the BLA for tab-cel. As part of these discussions, we expect to agree to reduce the amount of certain future potential regulatory and commercial milestone payments relating to tab-cel in the Additional Territory. We are also eligible to receive significant double-digit tiered royalties as a percentage of net sales of tab-cel (Ebvallo) in the Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel in each such country. Royalty payments may be reduced in certain specified customary circumstances. Royalties and milestones from the commercialization of Ebvallo in the Initial Territory remain subject to the HCRx Agreement.

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

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

In August 2024, we sold certain intermediates used in the manufacture of Ebvallo to Pierre Fabre for \$15.5 million, transferring title and risk of loss to these intermediates in advance of the Manufacturing Transition Date. We received payment for these intermediates in September 2024.

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

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

We and FUJIFILM Diosynth Biotechnologies California, Inc. (FDB) entered into a Master Services and Supply Agreement (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 cell therapy products (if approved) and product candidates, manufactured in accordance with cGMP standards. The Fujifilm MSA does not obligate us to purchase products and product candidates exclusively from FDB.

We also worked with Charles River Laboratories (CRL) pursuant to a Commercial Manufacturing Services Agreement (CRL MSA) that we entered into in December 2019. The CRL MSA expired on August 31, 2024 and we are currently in negotiations with CRL for a statement of work to support an orderly wind-down of manufacturing activities at CRL, transition of manufacturing activities of certain intermediates to FDB, and an orderly transition of manufacturing responsibility to PF upon the Manufacturing Transition Date.

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

In November 2023, we announced a reduction in force of approximately 30% of our workforce at that time. This workforce reduction resulted in total restructuring charges of \$6.7 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California Worker Adjustment and Retraining Notification (WARN) Act. In most cases, the severance payments were paid as a lump sum in January 2024. As of December 31, 2024, there are no remaining payments for the November 2023 reduction in force. All of the costs were cash expenditures and one-time termination benefits.

In January 2024, we announced a strategic reduction in workforce of approximately 25%. The workforce reduction resulted in total restructuring charges of \$5.1 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance payments were made during in the first half of 2024. Certain of the notified employees had employment agreements that provided for separation benefits in the form of salary continuation, which were paid from February 2024 through January 2025. As of December 31, 2024, approximately \$0.1 million of further separation payments and benefits are required for the January 2024 reduction in workforce. The majority of the associated costs are cash expenditures and primarily represent one-time termination benefits.

In January 2025, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (Response Letter) for the Biologics License Application (BLA) for tab-cel as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLTD), who have received at least one prior therapy including an anti-CD20 containing regimen. The Response Letter only cited findings that arose during a pre-license inspection of a third-party manufacturing facility for tab-cel. The Response Letter did not identify any deficiencies related to the manufacturing process, the clinical efficacy, or clinical safety data in the BLA, and the FDA did not request any new clinical trials to support a potential approval of tab-cel. Additionally, in January 2025, the FDA placed a clinical hold on Atara's active Investigational New Drug (IND) applications. These INDs include the tab-cel program as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLTD). The clinical hold is directly linked to inadequately addressed Good Manufacturing Practices (GMP) compliance issues referenced in the Response Letter. We are currently undertaking efforts to support this third-party manufacturer in addressing the FDA's requests to lift the clinical hold and to support resubmission of the BLA for tab-cel.

In January 2025, we announced another strategic reduction in workforce of approximately 50%. We expect to recognize approximately \$7.5 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2025. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from April 2025 through May 2026. The majority of the associated costs represent cash expenditures.

In March 2025, we announced a further strategic reduction in workforce of approximately 50%, retaining approximately 35 employees essential to executing on our strategic priorities. We expect to recognize approximately \$3.0 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2025. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from May 2025 through May 2026. The majority of the associated costs represent cash expenditures.

Financial Overview

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

Our net losses were \$85.4 million and \$276.1 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of \$2.1 billion. Substantially all of our net losses have resulted from costs incurred

in connection with our research and development programs and from general and administrative expenses associated with our operations. As of December 31, 2024, our cash, cash equivalents and short-term investments totaled \$42.5 million, which we intend to use to fund our operations.

Revenues

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

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

Cost of commercialization revenue

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

Research and Development Expenses

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

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

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

In addition, we believe it is important to invest in the development of new product candidates to continue to build the value of our product candidate pipeline and our business. We plan to continue to advance our most promising early product candidates into

preclinical development with the objective of advancing these early-stage programs to human clinical studies over the next several years.

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

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

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

General and Administrative Expenses

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

Interest Income

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

Interest Expense

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

Provision for Income Taxes

Provision for income taxes consists primarily of income taxes in U.S. states and foreign jurisdictions. Our effective tax rate was 0% for the years ended December 31, 2024 and 2023.

Critical Accounting Policies and Significant Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form

the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant judgments and estimates are detailed below, and our significant accounting policies are more fully described in Note 2 of the accompanying consolidated financial statements.

Revenue Recognition

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

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

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

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

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

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

Accrued Research and Development Expenses

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

Costs for preclinical studies, clinical studies and product candidate manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from, and discussions with, applicable personnel and outside service

providers as to the progress or state of completion of studies, or the goods and services delivered. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid asset and recognized as expense as the services are provided.

For the years ended December 31, 2024 and 2023, there were no material changes from our estimates of accrued research and development expenses. We do not believe there is a reasonable likelihood that there will be a material change in the future estimates of accrued research and development expenses. However, if actual results are not consistent with our estimates, we may be exposed to changes in accrued research and development expenses that could be material or the accrued research and development expenses reported in our financial statements may not be representative of the actual economic cost of accrued research and development.

Stock-based Compensation

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

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

- Expected term – We derived the expected term for employee stock awards using the “simplified” method (the expected term is determined as the average of the time-to-vesting and the contractual life of the options), as we have limited historical information to develop expectations about future exercise patterns and post vesting employment termination behavior. Expected term for non-employee awards is based on the remaining contractual term of an option on each measurement date.
- Expected volatility – In earlier periods, volatility was estimated using an average of our historical volatility and comparable public companies’ volatility for similar terms. Beginning in 2023, volatility is based solely on Atara’s historical stock price volatility.
- Expected dividend rate – We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore, we have assumed an expected dividend yield of 0%.
- Risk-free interest rate – The risk-free interest rate is based on the yields of U.S. Treasury securities with expected terms similar to that of the associated award.
- The fair value of our common stock is measured at the market price on the measurement date.

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

Accounting for Income Taxes

See Note 11 – “Income Taxes” in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for a complete discussion of the components of our income tax expense, if any, as well as the temporary differences that exist as of December 31, 2024.

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

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

We do not believe that there is a reasonable likelihood that there will be a material change in our liability for uncertain income tax positions or our effective income tax rate. However, if actual results are not consistent with our estimates or assumptions, we may be exposed to losses that could be material. We recorded a valuation allowance of approximately \$368.4 million as of December 31, 2024 related primarily to net operating loss carryforwards, capitalized research expenses, and tax credit carryforwards.

Liability related to the sale of future revenues

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

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

Revenues

Revenue consisted of the following in the periods presented:

	Year ended December 31,		Increase (Decrease)
	2024	2023	
	(in thousands)		
Commercialization revenue	\$ 128,940	\$ 7,886	\$ 121,054
License and collaboration revenues	—	687	(687)
Total revenue	<u>\$ 128,940</u>	<u>\$ 8,573</u>	<u>\$ 120,367</u>

Commercialization revenues were \$128.9 million in 2024 as compared to \$7.9 million in 2023. The increase in 2024 was due to revenue recognized as a result of the additional performance obligations identified pursuant to the A&R Commercialization Agreement, including, but not limited to, the \$46.7 million in fees related to transition plan activities for the year ended December 31, 2024, and the acceleration of the recognition period of the existing performance obligation related to the Initial Territory from the Pierre Fabre Commercialization Agreement.

Cost of commercialization revenue

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

	Year ended December 31,		Increase (Decrease)
	2024	2023	
	(in thousands)		
Cost of commercialization revenue	<u>\$ 21,009</u>	<u>\$ 8,886</u>	<u>\$ 12,123</u>

Costs of commercialization revenues were \$21.0 million in 2024 compared to \$8.9 million in 2023. The increase primarily related to an increased level of expense recognized associated with adjustments to reflect inventory at net realizable value, partially offset by a reduction of in-license sales-related milestone expense. Prior to receiving EC regulatory approval for Ebvallo in the EU in December 2022, we recorded all costs incurred in the manufacture of Ebvallo to be sold upon commercialization as research and development expense. As a result, Ebvallo inventories manufactured before EC regulatory approval, referred to as zero cost inventories, were expensed as research and development and are therefore excluded from the cost of commercialization revenue. Ebvallo manufacturing costs incurred after EC regulatory approval are capitalized into inventory and recorded into cost of commercialization revenue as the related commercialization revenue is recognized. The majority of commercialization revenue recognized to date associated with the sale of Ebvallo is related to zero cost inventories.

Research and development expenses

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

	Year ended December 31,		Increase (Decrease)
	2024	2023 (in thousands)	
Platform sciences, development and operations expense	\$ 77,444	\$ 122,940	\$ (45,496)
Medical and safety expense	44,138	67,445	(23,307)
Regulatory and quality expense	29,901	34,400	(4,499)
Total research and development expenses	<u>\$ 151,483</u>	<u>\$ 224,785</u>	<u>\$ (73,302)</u>

Platform sciences, development and operations expense were \$77.4 million in 2024 as compared to \$122.9 million in 2023. The decrease in 2024 was primarily due to lower payroll and related costs, driven by the November 2023 and January 2024 reductions in force and the termination of the ATA188 program after the Phase 2 EMBOLD study did not meet its primary endpoint.

Medical and safety expense were \$44.1 million in 2024 as compared to \$67.4 million in 2023. The decrease in 2024 is primarily due to lower payroll and related costs, driven by the November 2023 and January 2024 reductions in force and the close out of the ATA188 Phase 2 EMBOLD study after it did not meet its primary endpoint.

Regulatory and quality expense were \$29.9 million in 2024 as compared to \$34.4 million in 2023. The decrease in 2024 was primarily driven by lower payroll and related costs, driven by the November 2023 and January 2024 reductions in force. This decrease was partially offset by increased costs related to activities supporting the tab-cel BLA submission.

General and administrative expenses

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

	Year ended December 31,		(Decrease) Increase
	2024	2023 (in thousands)	
General and administrative expenses	<u>\$ 39,886</u>	<u>\$ 50,908</u>	<u>\$ (11,022)</u>

General and administrative expenses were \$39.9 million in 2024 as compared to \$50.9 million in 2023. The decrease in 2024 was primarily driven by lower payroll and related costs as a result of the November 2023 and January 2024 reductions in force.

Other income (expense), net

	Year ended December 31,		Increase (Decrease)
	2024	2023 (in thousands)	
Interest income	\$ 2,110	\$ 5,426	\$ (3,316)
Interest expense	(4,615)	(5,285)	670
Other income (expense), net	528	(246)	774
Total other income (expense), net	<u>\$ (1,977)</u>	<u>\$ (105)</u>	<u>\$ (1,872)</u>

Interest income was \$2.1 million in 2024, as compared to \$5.4 million in 2023. The decrease in 2024 was primarily driven by lower balances of cash, cash equivalents and available-for-sale securities.

Interest expense remained consistent in 2024 as compared to 2023.

Liquidity and Capital Resources

Sources of Liquidity

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

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

In January 2024, we completed a registered direct offering of pre-funded warrants to purchase 1,090,907 shares of common stock at a price of \$13.7475 per warrant. We received aggregate net proceeds of \$14.8 million after deducting offering expenses payable by us.

In September 2024, we completed a registered direct offering of 758,900 shares of common stock at an offering price of \$8.25 per share and pre-funded warrants to purchase 3,604,780 shares of common stock at an offering price of \$8.2499 per warrant. We received aggregate net proceeds of \$35.8 million after deducting offering expenses payable by us.

During the year ended December 31, 2024, we sold an aggregate of 492,855 shares of common stock under our ATM facilities, at an average price of \$19.23 per share, for gross proceeds of \$9.5 million and net proceeds of \$9.3 million, after deducting commissions and other offering expenses payable by us.

As of December 31, 2024, we had \$88.7 million of common stock remaining and available to be sold under the 2023 ATM Facility.

In January 2025, we announced that we had entered into a non-binding term sheet with Redmile Group to provide up to \$15 million in funding through an equity line of credit. We are also exploring alternative financing options.

We are in active discussions with Pierre Fabre on accelerating the transfer of all operational activities related to tab-cel, except the BLA sponsorship, to be completed as early as the end of the first quarter of 2025, as well as assumption by Pierre Fabre of certain costs related to the remediation of the third party manufacturing facility to address the FDA’s requests in order to lift the clinical hold and to support resubmission of the BLA for tab-cel. As part of these discussions, we expect to agree to reduce the amount of certain future potential regulatory and commercial milestone payments relating to tab-cel in the Additional Territory that we are entitled to receive, which could negatively impact our future cash flow.

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

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

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

December 31, 2024	December 31, 2023
(in thousands)	

Cash and cash equivalents	\$	25,030	\$	25,841
Short-term investments		17,466		25,884
Total cash, cash equivalents and short-term investments	\$	<u>42,496</u>	\$	<u>51,725</u>

Contractual Obligations and Commitments

We lease office space 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 moved our headquarters to Atara Research Center (ARC), our existing office, lab, and warehouse space in Thousand Oaks, California. In March 2021, we entered into a lease agreement for the 33,659 square feet of office, lab and warehouse space at ARC. 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.

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

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

In 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 7 – “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 9 – “Commitments and Contingencies” in the Notes to Consolidated Financial Statements, included in Item 8. Financial Statements and Supplementary Data of this report for further information on our contractual obligations and commitments.

Cash Flows

Comparison of the Years Ended December 31, 2024 and 2023

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (68,717)	\$ (192,977)
Investing activities	8,624	123,866
Financing activities	59,282	2,010
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (811)</u>	<u>\$ (67,101)</u>

Operating activities

Net cash used in operating activities was \$68.7 million in 2024 as compared to \$193.0 million in 2023. The decrease of \$124.3 million was primarily due to lower cash operating expenses in 2024 as compared to 2023, primarily due to lower compensation-related costs resulting from lower headcount driven by November 2023 and January 2024 reductions in force, as well as the \$40.0 million received from Pierre Fabre in 2023 for development milestones met in December 2022, with no similar cash flows received in 2024.

Investing activities

Net cash provided by investing activities in 2024 consisted of \$28.5 million received from maturities and sales of available-for-sale securities, partially offset by \$19.7 million used to purchase available-for-sale securities and \$0.2 million in purchases of property and equipment.

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

Financing activities

Net cash provided by financing activities in 2024 consisted primarily of \$50.6 million of net proceeds from sale of common stock and pre-funded warrants in registered direct offerings, and \$9.3 million of net proceeds from ATM facilities.

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

Operating Capital Requirements and Plan of Operations

We do not believe that our existing cash, cash equivalents and short-term investments are sufficient to fund our operations and ongoing activities in the near term, and believe that approximately \$15 million in additional financing is necessary to fund our ongoing activities required to achieve BLA approval for tab-cel. Such estimates are based on assumptions and plans that are subject to change and such changes could materially impact our expected cash runway. These assumptions include the planned transition of substantially all activities relating to tab-cel to Pierre Fabre by the end of the first quarter of 2025, as well as the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time. We do not know when, or if, we will generate sufficient revenue from commercialization to offset our operating expenses. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the accumulated losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need to raise substantial additional funding in the near term to finance our planned operations.

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

Our existing cash, cash equivalents and short-term investments as of December 31, 2024 will not be sufficient to fund our planned operations for at least the next 12 months after the date of issuance of these financial statements. These conditions raise substantial doubt about our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements.

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

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

- the timing, costs and results of our ongoing and planned clinical and preclinical studies for our product candidates;
- our success in establishing and maintaining manufacturing relationships with CMOs;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- subject to receipt of regulatory approval, costs associated with the commercialization of our product candidates by our partners and the amount of revenues received from commercial sales of our product candidates;
- the timing of proceeds from, and our ability to perform under, the A&R Commercialization Agreement, subject to the HCRx Agreement, as well as the terms and timing of any future commercialization, collaboration, licensing, partnering or other arrangements that we may establish;
- the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights;
- the extent to which we in-license or acquire other products and technologies; and
- the timing of the qualification of our CMOs' manufacturing facilities.

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

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2024, we had total cash, cash equivalents and short-term investments of \$42.5 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 decrease 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 shareholders 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, 2024 and 2023, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matter

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

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

Critical Audit Matter Description

The Company has entered into certain out-license agreements with Pierre Fabre Medicament ("Pierre Fabre").

During 2021, the Company entered into a Commercialization Agreement with Pierre Fabre. Under the terms of the agreement, the Company granted Pierre Fabre a license to commercialize and distribute Ebvallo in an initial territory and became responsible for manufacturing and supplying Ebvallo to Pierre Fabre, along with related cell selection services. In 2022, the Company entered into an Amendment Agreement to the Pierre Fabre Commercialization Agreement (the "PF Amendment No. 1"). Under the terms of the PF

Amendment No. 1, Atara became entitled to an additional milestone payment in exchange for, among other things, a reduction in: (i) royalties Atara is eligible to receive, and (ii) the price mark up on supply purchased by Pierre Fabre. Additionally, Atara also agreed to extend the time period for provision of certain services to Pierre Fabre under the Pierre Fabre Commercialization Agreement. In 2023, the Company entered into an amended and restated Pierre Fabre Commercialization Agreement (the "A&R Commercialization Agreement"). Under the terms of the A&R Commercialization Agreement, the Company granted Pierre Fabre an expanded license to commercialize and distribute Eballo in all other countries in the world and remains responsible for manufacturing and supplying Eballo to Pierre Fabre, along with related cell selection services until transfer of responsibility to Pierre Fabre.

In 2024, the Company entered into an agreement with Pierre Fabre to sell certain intermediates used in the manufacture of Eballo for \$15.5 million.

The Company recognizes revenue on the commercialization agreements with Pierre Fabre as they satisfy their performance obligations and when a customer obtains control of the promised goods or services. The revenue related to the commercialization agreements with Pierre Fabre is recognized within commercialization revenue within the Consolidated Statements of Operations and Comprehensive Loss. As of December 31, 2024, the Company recognized \$128.9 million of commercialization revenue and deferred revenue amounted to \$95.1 million, of which all \$95.1 million is included in current liabilities.

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

How the Critical Audit Matter Was Addressed in the Audit

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

- We reviewed and obtained an understanding of the Company's revenue generating agreements and related transactions during and at the end of the year via review of internal and external presentations, news and publications, and discussions with management.
- We evaluated the Company's conclusions related to the accounting for contract modifications.
- We evaluated management's determination that the agreements are within the scope of ASC 606 - Revenue from Contracts with Customers.
- We evaluated management's determination of the contractual term and the appropriateness of management's method to measure its progress over that term.
- We evaluated the assumptions used in the estimates of total costs and the estimated measure of progress for recognizing revenues by:
 - o Performing corroborating inquiries with the Company's project and business development managers, and comparing the assumptions used in the estimates to management's work plans, cost estimates and costs reported to date, and material rights allocated, accumulated and earned.
 - o Comparing costs incurred for activities completed to date to the costs forecasted for those activities.
 - o Comparing material rights accumulated and earned for activities completed to date to the fulfilment of performance obligations forecasted for those activities.

Testing the mathematical accuracy of management's revenue and current and long-term deferred revenue balances based on the estimated revenue to be recognized over time.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
March 7, 2025

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

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,030	\$ 25,841
Short-term investments	17,466	25,884
Restricted cash	146	146
Accounts receivable	1,482	34,108
Inventories	10,655	9,706
Other current assets	10,115	6,184
Total current assets	64,894	101,869
Property and equipment, net	1,294	3,856
Operating lease assets	39,807	54,935
Other assets	3,103	4,844
Total assets	<u>\$ 109,098</u>	<u>\$ 165,504</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 4,367	\$ 3,684
Accrued compensation	6,589	11,519
Accrued research and development expenses	7,984	17,364
Deferred revenue	95,092	77,833
Other current liabilities	20,542	31,826
Total current liabilities	134,574	142,226
Deferred revenue – long-term	—	37,562
Operating lease liabilities – long-term	29,914	45,693
Liability related to the sale of future revenues – long-term	38,624	34,623
Other long-term liabilities	3,269	4,631
Total liabilities	206,381	264,735
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Common stock—\$0.0001 par value, 500,000 shares authorized as of December 31, 2024 and 2023, respectively; 5,859 and 4,258 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1	—
Additional paid-in capital	1,957,261	1,870,123
Accumulated other comprehensive (loss) income	8	(204)
Accumulated deficit	(2,054,553)	(1,969,150)
Total stockholders' equity (deficit)	(97,283)	(99,231)
Total liabilities and stockholders' equity (deficit)	<u>\$ 109,098</u>	<u>\$ 165,504</u>

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,	
	2024	2023
Commercialization revenue	\$ 128,940	\$ 7,886
License and collaboration revenue	—	687
Total revenue	128,940	8,573
Costs and operating expenses:		
Cost of commercialization revenue	21,009	8,886
Research and development expenses	151,483	224,785
General and administrative expenses	39,886	50,908
Total costs and operating expenses	212,378	284,579
Loss from operations	(83,438)	(276,006)
Other income (expense), net:		
Interest income	2,110	5,426
Interest expense	(4,615)	(5,285)
Other income (expense), net:	528	(246)
Total other income (expense), net	(1,977)	(105)
Loss before provision for (benefit from) income taxes	(85,415)	(276,111)
Provision for (benefit from) income taxes	(12)	15
Net loss	\$ (85,403)	\$ (276,126)
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities	212	1,863
Comprehensive loss	\$ (85,191)	\$ (274,263)
Basic and diluted net loss per common share	\$ (11.41)	\$ (65.19)
Basic and diluted weighted-average shares outstanding	7,488	4,236

See accompanying notes to the consolidated financial statements.

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

	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of January, 1 2023	3,837	—	1,821,731	(2,067)	(1,693,024)
Issuance of common stock through ATM facilities, net of commissions and offering costs of \$351	122	—	2,172	—	2,172
Exercise of pre-funded warrants	116	—	—	—	—
RSU settlements, net of shares withheld	147	—	(94)	—	(94)
Issuance of common stock pursuant to employee stock awards	36	—	928	—	928
Stock-based compensation expense	—	—	45,386	—	45,386
Net loss	—	—	—	(276,126)	(276,126)
Unrealized gain (loss) on available-for-sale securities	—	—	—	1,863	1,863
Balance as of December 31, 2023	4,258	—	1,870,123	(204)	(1,969,150)
Issuance of common stock and pre-funded warrants to purchase common stock through a registered direct offering, net of offering costs of \$397	759	1	50,602	—	50,603
Issuance of common stock through ATM facilities, net of commissions and offering costs of \$168	493	—	9,312	—	9,312
Exercise of pre-funded warrants	9	—	—	—	—
RSU settlements, net of shares withheld	314	—	(7)	—	(7)
Issuance of common stock pursuant to employee stock awards	26	—	230	—	230
Stock-based compensation expense	—	—	27,001	—	27,001
Net loss	—	—	—	(85,403)	(85,403)
Unrealized gain (loss) on available-for-sale securities	—	—	—	212	212
Balance as of December 31, 2024	<u>5,859</u>	<u>\$ 1</u>	<u>\$ 1,957,261</u>	<u>\$ 8</u>	<u>\$ (2,054,553)</u>

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2024	2023
Operating activities		
Net loss	\$ (85,403)	\$ (276,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	27,001	45,386
Depreciation and amortization expense	5,051	4,829
Accretion of liability related to sale of future revenues	4,109	4,792
Non-cash operating lease expense	12,126	11,795
Amortization (accretion) of investment premiums	(240)	792
Other non-cash items, net	(402)	214
Changes in operating assets and liabilities:		
Accounts receivable	32,626	6,113
Inventories	(4,434)	(8,120)
Other current assets	(1,227)	273
Other assets	19	1,043
Accounts payable	687	(3,130)
Accrued compensation	(4,930)	(6,140)
Accrued research and development expenses	(9,380)	(3,663)
Other current liabilities	(12,504)	11,064
Deferred revenue	(20,303)	30,395
Operating lease liabilities	(11,051)	(12,636)
Other long-term liabilities	(462)	142
Net cash used in operating activities	(68,717)	(192,977)
Investing activities		
Purchases of short-term investments	(19,665)	(83,648)
Proceeds from maturities and sales of short-term investments	28,535	208,712
Purchases of property and equipment	(246)	(1,223)
Proceeds from sale of property and equipment	—	25
Net cash provided by (used in) investing activities	8,624	123,866
Financing activities		
Proceeds from sale of common stock and pre-funded warrants in registered direct offerings, net	50,603	—
Proceeds from issuance of common stock through ATM facilities, net	9,348	2,136
Proceeds from employee stock awards	230	928
Taxes paid related to net share settlement of restricted stock units	—	(94)
Principal payments on finance lease obligations	(892)	(947)
Other financing activities, net	(7)	(13)
Net cash provided by financing activities	59,282	2,010
Increase (decrease) in cash, cash equivalents and restricted cash	(811)	(67,101)
Cash, cash equivalents and restricted cash at beginning of period	25,987	93,088
Cash, cash equivalents and restricted cash at end of period	<u>\$ 25,176</u>	<u>\$ 25,987</u>
Non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and other accrued liabilities	<u>\$ —</u>	<u>\$ 132</u>
Accrued costs related to ATM facilities	<u>\$ —</u>	<u>\$ 78</u>
Proceeds from issuance of common stock through ATM facilities not yet received	<u>\$ —</u>	<u>\$ 114</u>
Supplemental cash flow disclosure		
Cash paid for interest	<u>\$ 685</u>	<u>\$ 447</u>
Cash paid for income taxes	<u>\$ 24</u>	<u>\$ 2</u>

See accompanying notes to the consolidated financial statements.

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.

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

We have licensed rights to T-cell product candidates from Memorial Sloan Kettering Cancer Center (MSK), rights related to our next-generation CAR T programs from MSK, and rights to know-how and technology from the Council of the Queensland Institute of Medical Research (QIMR Berghofer). See Note 9 for further information.

In November 2023, we announced a reduction in force that reduced our workforce by approximately 30%. We recognized \$6.7 million in total for severance and related benefits for employees laid off under the reduction in force. These charges are one-time termination benefits and are all cash charges. In January 2024, we announced a strategic reduction in workforce of approximately 25%. We recognized \$5.1 million in total for severance and related benefits for employees laid off under the reduction in force. These charges are one-time termination benefits and are all cash charges. The majority of the associated costs are cash expenditures and primarily represent one-time termination benefits. Refer to Note 8 for further information.

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 President & Chief Executive Officer, who is our chief operating decision maker (CODM), reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. The CODM assesses performance for the business and decides how to allocate resources based on net loss that also is reported on the income statement as consolidated net loss. The CODM uses net loss to monitor expenditures and budget versus actual results. The measure of segment assets is reported on the balance sheet as total consolidated assets. The following tables represent information provided to the chief operating decision maker:

	Year Ended December 31,			
	2024		2023	
Revenue	\$	128,940	\$	8,573
Less:				
Cost of commercialization revenue		21,009		8,886
Platform sciences, development and operations expense		77,444		122,940
Medical and safety expense		44,138		67,445
Regulatory and quality expense		29,901		34,400
General and administrative expense		39,886		50,908
Other segment items*		1,965		120
Net loss		(85,403)		(276,126)

*Other segment items include Other Income (expense), net and Provision for (benefit from) income taxes

Substantially all of our assets are located in the U.S. All commercialization and collaboration revenue recognized in 2024 and 2023 related to our agreements with Pierre Fabre, a French company.

Use of Estimates

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

June 2024 Reverse Stock Split

At our annual meeting of stockholders held on June 10, 2024, the stockholders of Atara approved a proposal to authorize our Board of Directors (the Board) to amend our Amended and Restated Certificate of Incorporation to effect a reverse stock split. The Board approved the reverse stock split on June 10, 2024 and, on June 20, 2024, we effected a 1-for-25 reverse stock split of our common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse stock split. All equity related information including per share amounts for all periods presented in these condensed consolidated financial statements and the notes thereto have been adjusted retroactively, where applicable, to reflect the effect of this reverse stock split.

Liquidity Risk

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

Going Concern

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

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, we plan to secure additional capital, potentially through a combination of public or private security offerings; use of our ATM facility as described in Note 10; and/or strategic transactions. We may need to raise additional funding as required based on the status of our development programs and our projected cash flows. Although we have been successful in raising capital in the past, and expect to continue to raise capital as required, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If we are unable to obtain sufficient funding on acceptable terms, we could be forced to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates, which could have a material adverse effect on our business, results of operations, and financial condition. Accordingly, we have concluded that substantial doubt exists with respect to our ability to continue as a going concern for at least 12 months after the issuance of the accompanying consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Concentration of Credit Risk and Other Uncertainties

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

Currency Translation

Transactions and monetary assets and liabilities that are denominated in a foreign currency are translated into U.S. dollars at the current exchange rate on the transaction date and as of each balance sheet date, respectively, with gains or losses on foreign exchange changes recognized in interest and other income (expense), net in the consolidated statements of operations and comprehensive loss. Foreign currency-denominated monetary assets and liabilities as of December 31, 2024 were not material.

Cash, Cash Equivalents and Short-Term Investments

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

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

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

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

Changes in the fair value of available-for-sale securities impact the consolidated statements of operations and comprehensive loss only when such securities are sold, if an allowance for credit losses is recognized or if an impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. We regularly review our investment portfolio to determine if any security is impaired, which would require us to record an allowance for credit losses or impairment charge in the period any such determination is made. In making this judgment, we evaluate, among other things, the duration and extent to which the fair value of a security is less than its cost, our intent to sell or whether it is more likely than not that

we will be required to sell the security before recovery of its amortized cost basis, the financial condition of the issuer and any changes thereto, and, as necessary, the portion of a decline in fair value that is credit-related. This assessment could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses, allowances for credit losses and impairments on available-for-sale securities, if any, are recorded to other income (expense), net in the statements of operations and comprehensive loss.

Fair Value Measurement

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

Financial Instruments

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

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

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

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

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

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

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

Accounts Receivable, net

Accounts receivable are primarily amounts due from our commercialization partner.

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

Inventories

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

We begin capitalizing costs as inventory when the product candidate receives regulatory approval and when the manufacturing facility producing such inventory is qualified by the relevant regulatory agency. Prior to regulatory approval and facility 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 assess the recoverability of our inventory each reporting period and reduce the carrying value of the inventory when items are determined to be obsolete, defective or in excess of forecasted production requirements. Inventory write-downs for excess, defective and obsolete inventory are recorded within cost of commercialization revenue.

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 expensed as incurred.

Long-lived Assets

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

Asset Retirement Obligation (ARO)

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

Leases

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

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

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

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

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

Accruals of Research and Development Costs

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

Sale of Future Revenues

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

Revenue Recognition

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

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

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

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

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

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

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

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

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

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

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

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

Cost of commercialization revenue

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

In 2024 and 2023, cost of commercialization revenue included adjustments of \$18.5 million and \$6.6 million, respectively, to write-off of inventories and to reflect them at the lower of cost or net realizable value.

Research and Development Expense

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

Stock-Based Compensation Expense

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

In determining the fair value of stock option awards granted, we use the Black-Scholes valuation model and assumptions include:

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

Expected volatility – Expected volatility is estimated based on the historical volatility of Atara’s stock price historical volatility for the same period of time as the expected term of the associated award.

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, 2024 and 2023 we recorded matching contributions of approximately \$1.2 million and \$1.9 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, 2024 and 2023. We intend to maintain valuation allowances until sufficient evidence exists to support their reversal.

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

Comprehensive Income (Loss)

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

Recent Accounting Pronouncements

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

In December 2023, the FASB issued ASU No. 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires enhancements to certain income tax disclosures, most notably the income tax rate reconciliation and income taxes paid. We will adopt the amendments effective for the fiscal year ending December 31, 2025. We do not expect the adoption of this standard will have a material impact on our disclosures.

In November 2024, the FASB issued ASU No. 2024-03 Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40), which requires disclosure of additional information about specific expense categories underlying certain income statement expense line items. This ASU is effective for our annual periods beginning October 1, 2027, and requires either prospective or retrospective application. We are currently evaluating the impact of the ASU on our disclosures.

3. Net Loss per Common Share

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

Potential dilutive securities, which include unvested RSUs, unvested performance-based RSUs and performance-based options to purchase common stock for which established performance criteria have been achieved as of the end of the respective periods, vested and unvested options to purchase common stock and shares to be issued under our employee stock purchase plan (ESPP), have been excluded from the computation of diluted net loss per common 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,	
	2024	2023
Unvested RSUs	414,470	250,449
Vested and unvested options	222,333	428,266
ESPP share purchase rights	5,971	7,434
Total	<u>642,774</u>	<u>686,149</u>

4. Financial Instruments

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

As of December 31, 2024:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	\$ 13,718	\$ —	\$ —	\$ 13,718
U.S. Treasury obligations	Level 2	27,450	8	—	27,458
Total available-for-sale securities		41,168	8	—	41,176
Less: amounts classified as cash equivalents		(23,708)	(2)	—	(23,710)
Amounts classified as short-term investments		<u>\$ 17,460</u>	<u>\$ 6</u>	<u>\$ —</u>	<u>\$ 17,466</u>

As of December 31, 2023:	Input Level	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Estimated Fair Value
			(in thousands)		
Money market funds	Level 1	\$ 14,376	\$ —	\$ —	\$ 14,376
U.S. Treasury obligations	Level 2	9,928	1	—	9,929
Corporate debt obligations	Level 2	26,089	—	(205)	25,884
Total available-for-sale securities		50,393	1	(205)	50,189
Less: amounts classified as cash equivalents		(24,304)	(1)	—	(24,305)
Amounts classified as short-term investments		<u>\$ 26,089</u>	<u>\$ —</u>	<u>\$ (205)</u>	<u>\$ 25,884</u>

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

	As of December 31, 2024		As of December 31, 2023	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
	(in thousands)		(in thousands)	
Maturing within one year	\$ 41,168	\$ 41,176	\$ 50,393	\$ 50,189
Maturing in one to five years	—	—	—	—
Total available-for-sale securities	<u>\$ 41,168</u>	<u>\$ 41,176</u>	<u>\$ 50,393</u>	<u>\$ 50,189</u>

We considered the current and expected future global economic and market conditions, including, but not limited to, the wars in Ukraine and the Middle East and increased tensions between the U.S. and China, and determined that our investments have not been significantly impacted. As of December 31, 2024, 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, 2024 and 2023, 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, 2024 and 2023, accrued interest receivable was immaterial. 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, 2024 and 2023.

In addition, restricted cash collateralized by a certificate of deposit 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, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	\$ 25,030	\$ 25,841
Restricted cash – short-term	146	146
Total cash, cash equivalents and restricted cash	<u>\$ 25,176</u>	<u>\$ 25,987</u>

5.Out-license Agreements

Pierre Fabre Agreements

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

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

Pierre Fabre paid us an upfront cash payment of \$45.0 million for the exclusive license grant for the Initial Territory in the fourth quarter of 2021. In December 2022, we met the contractual right to receive \$40.0 million in milestone payments upon certain regulatory milestones, for which the cash was received in January 2023. Subject to the terms of the royalty purchase agreement with HCRx, as described in Note 6, we are entitled to receive an aggregate of up to \$308.0 million in remaining milestone payments upon achieving certain regulatory and commercial milestones in addition to double-digit tiered royalties as a percentage of net sales of Ebvallo in the Initial Territory, until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights, or the expiration of all regulatory exclusivity for Ebvallo on a country-by-country basis. In December 2023, upon the effective date of the A&R Commercialization Agreement, we met the contractual right to receive an additional upfront cash payment of \$20.0 million for the expanded exclusive license grant in the Additional Territory, for which the cash was received in January 2024. In March 2024, we met the contractual right to receive \$20.0 million in milestone payments upon achieving a regulatory milestone, for which the cash was received in April 2024. In July 2024, we met the contractual right to receive an additional \$20.0 million in milestone payments upon achieving acceptance of our biologics license application (BLA) for tab-cel by the United States Food and Drug Administration (FDA) and we received the cash in August 2024. We will also be entitled to receive an aggregate of up to \$580.0 million in additional payments upon achieving certain regulatory and commercial milestones relating to tab-cel in the Additional Territory. We will be eligible to receive double-digit tiered royalties as a percentage of net sales of tab-cel in

the Additional Territory until the later of 12 years after the first commercial sale in each such country, the expiration of specified patent rights in each such country, or the expiration of all regulatory exclusivity for tab-cel on a country-by-country basis.

We have entered into a separate manufacturing and supply agreement with Pierre Fabre for us to manufacture Ebvallo for Pierre Fabre to use in the Initial Territory based on a fixed price through December 31, 2023 and at a price equal to cost plus a margin for orders placed after December 31, 2023, subject to a maximum annual increase. Pierre Fabre will assume the responsibility and cost for the manufacture and supply of tab-cel (Ebvallo) in the Territory upon the Manufacturing Transition Date, which is defined as the earlier of: i) all activities relating to the transfer of tab-cel manufacturing, pursuant to the A&R Commercialization Agreement, from Atara to Pierre Fabre have been completed to the reasonable satisfaction of both parties, or ii) December 31, 2025, through the remainder of the term of the A&R Commercialization Agreement. Pierre Fabre and we are to use commercially reasonable efforts to achieve this prior to the earlier transfer date from Atara to Pierre Fabre of the first marketing authorization in the Additional Territory or the first BLA (PF Transfer Date). Prior to the Manufacturing Transition Date, we are responsible for manufacturing and supplying tab-cel (Ebvallo) to Pierre Fabre in the Territory. Without transfer of the manufacturing technology, no other party can manufacture tab-cel (Ebvallo).

In August 2024, we sold certain intermediates used in the manufacture of Ebvallo to Pierre Fabre for \$15.5 million, transferring title and risk of loss to these intermediates in advance of the Manufacturing Transition Date, which guarantees Pierre Fabre supply and control of intermediates to be used in the production of Ebvallo. We received payment for these intermediates in September 2024.

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

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

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

Accounting Analysis

Identification of the Contract

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

Identification of the Promises and Performance Obligations

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

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

(2) the transfer of intellectual property rights in the form of a license in the Additional Territory, the manufacture and supply of tab-cel and the performance of cell-selection services, as well as the promises to transfer the related technologies, and

perform certain development, safety, regulatory and information technology transition services. We concluded that the promises are not distinct because Pierre Fabre cannot benefit from the license without the other services and vice versa. Consequently, these promises represent a single performance obligation, collectively referred to as the Additional Territory Obligation.

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

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

Determination of the Transaction Price

Under the Pierre Fabre Commercialization Agreement, we determined that the \$45.0 million upfront payment constituted the entire consideration to be included in the transaction price at the outset of the arrangement, and the \$40.0 million in regulatory milestones achieved in December 2022 were added to the transaction price upon meeting the related milestone criteria. The remaining potential regulatory 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 reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, as necessary, we adjust our estimate of the transaction price.

Upon the effective date of the A&R Commercialization Agreement, the \$20.0 million additional upfront payment received and estimated revenue for the development, safety, regulatory and process science services were added to the transaction price, and the \$20.0 million regulatory milestone achieved in March 2024 and the \$20.0 million regulatory milestone achieved in July 2024 were added to the transaction price upon meeting the related milestone criteria. The remaining potential regulatory 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.

Allocation of the Transaction Price to Performance Obligations

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

Recognition of Revenue

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

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

Deferred revenue activity related to commercialization revenue for the year ended December 31, 2024 was as follows:

		Total (in thousands)
Deferred revenue, December 31, 2023	\$	115,395
Additions		105,235
Recognized into commercialization revenue		(125,538)
Deferred revenue December 31, 2024		95,092
Less: deferred revenue – current portion		(95,092)
Deferred revenue – long-term, December 31, 2024	\$	<u>—</u>

During the year ended December 31, 2024, we recognized \$45.7 million of revenue that was included in the deferred revenue balance as of December 31, 2023. During the year ended December 31, 2024, we recognized revenue of \$0.9 million related to performance obligations partially satisfied in prior periods related to changes in the transaction price upon achievement of development milestones.

Costs incurred relating to performing the services within the Additional Territory Obligation and Process Sciences Obligation consist of third party expenses and for time incurred by our employees to satisfy requirements set forth by the A&R Commercialization Agreement. These costs are included in research and development expenses in the consolidated statements of operations and comprehensive income (loss) during the year ended December 31, 2024 and 2023. Such costs were \$43.3 million for the year ended December 31, 2024 and were not material for the year ended December 31, 2023.

6. Liability Related to the Sale of Future Revenues

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

Under the HCRx Agreement, HCRx is entitled to receive tiered royalties on net sales of Ebvallo in the Initial Territory in amounts ranging from the mid-single digits to double digits based on annual net sales. HCRx is also entitled to certain milestone payments due to Atara from Pierre Fabre. The total royalties and milestones payable to HCRx are capped between 185% and 250% of the Investment Amount, depending upon the timing of such royalties and milestones. Upon meeting the cap amount, HCRx's right to receive royalties and milestone payments will terminate and all rights will revert to Atara. To the extent a certain milestone within the Pierre Fabre Commercialization Agreement is not achieved on or prior to June 30, 2026, we will be required to make a one-time cash payment in the amount of \$9.0 million to HCRx, and HCRx shall transfer all of its right, title and interest in this certain \$9.0 million milestone payment to Atara. This payment, if required, would be included in the calculation of aggregate payments made to HCRx.

The gross proceeds of the Investment Amount of \$31.0 million were recorded as a liability related to the sale of future revenues, net of transaction costs of \$0.4 million, and is 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 estimate the effective interest rate used to record non-cash interest expense under the HCRx Agreement based on the estimate of future royalty payments to be received by HCRx. As of December 31, 2024, the annual effective interest rate was approximately 10%. Over the life of the arrangement, the actual effective interest rate will be affected by the amount and timing of the actual and forecasted royalty and milestone payments to HCRx. At each reporting date, we reassess our estimate of the timing and amounts of future payments made to HCRx, and prospectively adjust the effective interest rate and amortization of the liability as necessary.

The following table presents the changes in the liability related to the sale of future revenues under the HCRx Agreement for the year ended December 31, 2024:

	(in thousands)
Liability related to sale of future revenues as of December 31, 2023	\$ 35,076
Accretion of interest expense on liability related to sale of future revenues	4,109
Amortization of debt discount and debt issuance costs	67
Repayment of the liability	(246)
Liability related to sale of future revenues as of December 31, 2024	39,006
Less: current portion classified within other accrued liabilities	(382)
Long-term liability related to sale of future revenues	<u>\$ 38,624</u>

7. Leases

In November 2018, we entered into a lease agreement for office space in Thousand Oaks, California, that expires in February 2026 and for which we have the option to extend the lease for an additional period of five years after the initial term. In February 2025, we moved our headquarters to Atara Research Center (ARC), our existing office, lab, and warehouse space in Thousand Oaks, California. In March 2021, we entered into a lease agreement for the 33,659 square feet of office, lab and warehouse space at ARC. 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 and in November 2023, we further amended the lease agreement for our office and lab space in Aurora, Colorado, to extend the term of the lease agreement to April 2025.

In February 2017, we entered into a lease agreement (the ATOM Lease) for approximately 90,580 square feet of office, lab and cellular therapy manufacturing space in Thousand Oaks, California. The initial 15-year term of the headlease commenced on February 15, 2018, upon the substantial completion of landlord's work as defined under the agreement. In April 2022, we assigned the ATOM Lease to FDB in connection with the closing of the sale of the ATOM Facility to FDB. Under ASC 842, we are considered to be the sub-lessor of the ATOM Lease. We have not received novation from the landlord and therefore have not been relieved of our primary obligations under the headlease. Therefore, the ROU asset and lease liability for the ATOM Facility remain on our balance sheet.

We evaluated our vendor contracts to identify embedded leases and determined that the Fujifilm MSA contained items that constituted a lease under ASC 842, Leases, as Atara has the right to substantially all of the economic benefits from the use of the asset and can direct the use of the asset. We concluded that the Fujifilm MSA contains an embedded operating lease for certain dedicated processing rooms for the manufacturing of Atara product and an embedded finance lease for certain freezers dedicated for our use. The Fujifilm MSA includes contractual obligations in the form of payments for the processing rooms and the freezers, each over a term of five years. As a result, we added ROU assets and lease liabilities for the processing rooms and freezers for the initial term of the lease in the amounts of \$50.8 million and \$4.8 million, respectively. In November 2023, we agreed to forego the use of one processing room for approximately one year in return for a reduction in contractual obligations under the Fujifilm MSA, and in November 2024, we exercised the option to release the processing room to FDB for the remainder of the initial term.

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

The maturities of lease liabilities under our operating and finance leases as of December 31, 2024 were as follows:

Years Ending December 31,	Operating Leases		Finance Leases	
	(in thousands)			
2025	\$	17,004	\$	1,263
2026		15,677		1,285
2027		5,494		437
2028		3,319		—
2029		3,415		—
Thereafter		9,044		—
Total lease payments	\$	53,953	\$	2,985
Less: amount representing interest		(11,160)		(346)
Present value of lease liabilities	\$	<u>42,793</u>	\$	<u>2,639</u>
Balance as of December 31, 2024				
Other current liabilities	\$	12,879	\$	1,038
Operating lease liabilities – long-term		29,914		—
Other long-term liabilities		—		1,601
Total	\$	<u>42,793</u>	\$	<u>2,639</u>

The components of lease cost were as follows:

	Year Ended		Year Ended	
	December 31, 2024		December 31, 2023	
(in thousands)				
Operating lease cost:				
Operating lease cost	\$	16,930	\$	17,192
Short-term lease cost		193		201
Total operating lease cost	\$	<u>17,123</u>	\$	<u>17,393</u>
Finance lease cost:				
Amortization expense	\$	959	\$	976
Interest on lease liabilities		326		416
Total finance lease cost	\$	<u>1,285</u>	\$	<u>1,392</u>

Other information related to leases was as follows:

	Year Ended December 31, 2024	Year Ended December 31, 2023
(in thousands, except lease term and discount rate)		
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ 16,019	\$ 16,660
Operating cash flows for finance leases	326	416
Financing cash flows for finance leases	892	947
Operating lease assets obtained in exchange for lease obligations:	\$ —	\$ 312
Finance lease assets obtained in exchange for lease obligations:	—	—
Non-cash (decrease) increase to operating lease assets due to remeasurement of lease liabilities:	(3,002)	(1,589)
Weighted Average Remaining Lease Term		
Operating leases	4.7 years	5.2 years
Finance leases	2.3 years	3.3 years
Weighted Average Discount Rate		
Operating leases	11.2 %	11.4 %
Finance leases	10.4 %	10.4 %

Asset Retirement Obligation

Our asset retirement obligation (ARO) consists of a contractual requirement to remove the tenant improvements at the ATOM Facility in Thousand Oaks, California and restore the facility to a condition specified in the lease agreement. Although we assigned the ATOM Lease to FDB in connection with the closing of the sale of the ATOM Facility to FDB in April 2022, we have not received novation from the landlord. Therefore, the ARO associated with the ATOM Facility remains on our balance sheet. We recorded an estimate of the fair value of our ARO liability in other long-term liabilities and the ARO asset as a long-term asset in the period incurred. The fair value of the ARO asset is amortized over the lease term. The fair value of our ARO was estimated by discounting projected cash flows over the estimated life of the related assets using our credit adjusted risk-free rate. As of December 31, 2024 and December 31, 2023, the ARO asset and liability were not material.

8. Restructuring

On August 8, 2022 we announced a strategic reduction in workforce of approximately 20% to focus our activities as an organization centered on research and development. The workforce reduction included total restructuring charges of \$6.0 million, comprised primarily of severance payments, wages for the 60-day notice period in accordance with the California Worker Adjustment and Retraining Notification (WARN) Act and continuing health care coverage for a period of time after separation. In most cases, the severance payments were paid as a lump sum in October 2022. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits were paid between October 2022 and November 2023, and there are no further payments required for this reduction in workforce as of December 31, 2024. All of the costs were cash expenditures and represented one-time termination benefits.

On November 1, 2023 we announced a strategic reduction in workforce of approximately 30%. The workforce reduction resulted in total restructuring charges of \$6.7 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance payments were paid as a lump sum in January 2024. As of December 31, 2024, there are no remaining payments for the November 2023 reduction in workforce. All of the costs are cash expenditures and represent one-time termination benefits.

On January 8, 2024, we announced a strategic reduction in workforce of approximately 25%. The workforce reduction resulted in total restructuring charges of \$5.1 million, comprised primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance payments were paid during the first half of 2024. Certain of the notified employees had employment agreements that provided for separation benefits in the form of salary continuation, which are being paid from February 2024 through January 2025. As of December 31, 2024, \$0.1 million of further separation payments and

benefits are required for the January 2024 reduction in workforce. The majority of the associated costs are cash expenditures and primarily represent one-time termination benefits.

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

	Year Ended December 31, 2024	(in thousands)	Year Ended December 31, 2023
Research and development expense	\$	3,750	\$ 5,619
General and administrative expense		1,357	1,111
Total restructuring charges	\$	<u>5,107</u>	<u>\$ 6,730</u>

The following restructuring liability activity was recorded in connection with the reduction in force for the year ended December 31, 2024, with all of the \$0.1 million liability balance as of December 31, 2024 included within other current liabilities on the accompanying consolidated balance sheet:

	Year ended December 31, 2024	(in thousands)	Year ended December 31, 2023
Liability balance, January 1	\$	4,923	\$ 1,545
Restructuring charges		5,107	6,730
Cash payments		(9,298)	(3,352)
Non-cash settlements/adjustments		(669)	—
Liability balance, December 31	\$	63	\$ 4,923

9. Commitments and Contingencies

MSK In-License Agreements

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

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

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

In March 2024, we terminated our license agreements with MSK to the ATA2271 and ATA3271 programs targeting mesothelin.

QIMR Berghofer In-License Agreements

In October 2015, we entered into an exclusive license agreement and a research and development collaboration agreement with QIMR Berghofer. Under the terms of the license agreement, we obtained an exclusive, worldwide license to develop and commercialize allogeneic T-cell therapy programs utilizing technology and know-how developed by QIMR Berghofer. In September 2016, the exclusive license agreement and research and development collaboration agreement were amended and restated. Under the amended and restated agreements, we obtained an exclusive, worldwide license to develop and commercialize additional T-cell programs, as well as the option to license additional technology that we exercised in June 2018. We further amended and restated our

license agreement and research and development collaboration agreements with QIMR Berghofer in August 2019, August 2020 and December 2021, in each case, to terminate our license to certain rights. Our current license agreement also provides for various milestone and royalty payments to QIMR Berghofer based on future product sales, if any. Under the terms of our current research and development collaboration agreement, we are also required to reimburse the cost of agreed-upon development activities related to programs developed under the collaboration. These payments are expensed on a straight-line basis over the related development periods. The agreement also provides for various milestone payments to QIMR Berghofer based on achievement of certain developmental and regulatory milestones. We are in discussions with QIMR Berghofer to return rights to ATA188 and the EBV vaccine to QIMR Berghofer.

Other In-license and Collaboration Agreements

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

Milestones and royalties under each of the above agreements are contingent upon future events and will be recorded as expense when the underlying milestones are achieved or royalties are earned. Sales related milestone and royalty costs related to Ebvallo are recorded in cost of commercialization revenue, whereas regulatory milestone costs are recorded in research and development expense. As of December 31, 2024 and 2023, 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. The CRL MSA expired on August 31, 2024 and we are currently in negotiations with CRL for a statement of work to support an orderly wind-down of manufacturing activities at CRL, transition of manufacturing activities of certain intermediates to FDB, and an orderly transition of manufacturing responsibility to PF upon the Manufacturing Transition Date.

Fujifilm Master Services and Supply Agreement

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

Other Research, Development and Manufacturing Agreements

We may enter into other contracts in the normal course of business with clinical research organizations for clinical trials, with CMOs for product, product candidates and clinical supplies, and with other vendors for preclinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination on notice. As of December 31, 2024 and December 31, 2023, there were no material amounts accrued related to contract termination charges.

Minimum Commitments

The non-cancellable minimum commitments for products and services, subject to agreements with a term of greater than one year with clinical research organizations and CMOs, excluding those recognized on our balance sheet, as of December 31, 2024 are set forth below:

Calendar Year	Remaining Minimum Commitment as of December 31, 2024 (in thousands)
2025	13,308
2026	9,605
2027	3,388
Total	<u>\$ 26,301</u>

We have incurred \$14.1 million and \$19.4 million against such minimum commitments for the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024 and December 31, 2023, we have accrued \$5.3 million and \$11.2 million in research and development expenses related to minimum purchase commitments.

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we consider the fair value of these indemnification agreements to be minimal. Accordingly, we did not record liabilities for these agreements as of December 31, 2024 and 2023.

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.

During the third quarter of 2024, MSK sent us a notice alleging that under the terms of our license agreements with MSK, MSK is entitled to \$6.0 million of sub-licensing fees as a result of the \$60.0 million we received from Pierre Fabre related to the Additional Territory upfront and milestone payments in 2024 pursuant to the A&R Commercialization Agreement. We do not believe we owe the \$6.0 million to MSK under the terms of our license agreements with MSK and have entered into evaluative non-binding mediation with MSK to potentially resolve this disagreement. We paid the \$6.0 million to MSK under protest in the third quarter of 2024 in order to proceed with the dispute process per the terms of the license agreements. We recorded this cost in research and development expenses on the consolidated statements of operations and comprehensive income (loss) during the year ended December 31, 2024. There is no guarantee we will reach a favorable outcome in the mediation or on this matter and we may owe a portion of future milestones we receive from Pierre Fabre to MSK.

10. Stockholders' Equity (Deficit)

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, 2024 and 2023.

Equity Offerings

As part of our July 2019 underwritten public offering, we issued and sold pre-funded warrants to purchase 117,801 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 \$0.0025 per share and expires seven years from the date of issuance. These warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise (the 2019 Warrant Maximum Ownership Percentage). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the 2019 Warrant Maximum Ownership Percentage to any other percentage not to exceed 19.99%. No July 2019 pre-funded warrants were exercised during the year ended December 31, 2024, and, as of December 31, 2024, pre-funded warrants to purchase 101,089 shares of our common stock from the July 2019 underwritten public offering were outstanding.

As part of the May 2020 underwritten public offering, we issued and sold pre-funded warrants to purchase 114,678 shares of common stock in an underwritten public offering pursuant to a shelf registration on Form S-3.

Additionally, as part of the December 2020 underwritten public offering, we issued and sold pre-funded warrants to purchase 81,632 shares of common stock in an underwritten public offering pursuant to a shelf registration on Form S-3. These warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital.

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. No May 2020 or December 2020 pre-funded warrants were exercised during the year ended December 31, 2024. As of December 31, 2024, 38,735 and 55,387 of the pre-funded warrants to purchase shares of our common stock issued and sold as part of the May 2020 and December 2020 underwritten public offerings, respectively, were outstanding.

In January 2024, we issued and sold pre-funded warrants to purchase 1,090,907 shares of common stock at a price of \$13.7475 per warrant in a registered direct offering pursuant to a shelf registration on Form S-3. The gross proceeds from this sale were \$15.0 million, resulting in net proceeds of \$14.8 million after deducting offering expenses payable by us.

Each of the January 2024 pre-funded warrants issued entitles the holder to purchase one share of common stock at an exercise price of \$0.0025 per share, with no expiration date. These warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise (the January 2024 Maximum Ownership Percentage). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the January 2024 Maximum Ownership Percentage to any other percentage not to exceed 19.99%. No January 2024 pre-funded warrants were exercised during the year ended December 31, 2024 and all 1,090,907 of the January 2024 pre-funded warrants remain outstanding as of December 31, 2024.

In September 2024, we issued and sold 758,900 shares of common stock at an offering price of \$8.25 per share and pre-funded warrants to purchase 3,604,780 shares of common stock at an offering price of \$8.2499 per warrant in a registered direct offering pursuant to a shelf registration on Form S-3. The gross proceeds from this sale were \$36.0 million, resulting in net proceeds of \$35.8 million after deducting offering expenses payable by us.

Each of the September 2024 pre-funded warrants issued entitles the holder to purchase one share of common stock at an exercise price of \$0.0001 per share, with no expiration date. These warrants were recorded as a component of stockholders' equity (deficit) 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, at the holder's election, 4.99%, 9.99% or 19.99% after giving effect to the exercise (the September 2024 Warrant Maximum Ownership Percentage). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the September 2024 Warrant Maximum Ownership Percentage to any other percentage not to exceed 19.99%.

During the year ended December 31, 2024, 8,634 of the September 2024 pre-funded warrants were exercised, and as of December 31, 2024, pre-funded warrants to purchase 3,596,146 shares of our common stock from the September 2024 direct offering were outstanding.

ATM Facilities

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

During the year ended December 31, 2023, we sold an aggregate of 3,038,432 shares of common stock under the 2021 ATM Facility, at an average price of \$0.83 per share, for gross proceeds of \$2.5 million and net proceeds of \$2.2 million, after deducting commissions and other offering expenses payable by us. Approximately \$0.1 million of the \$2.2 million net proceeds were received on January 2, 2024.

During the year ended December 31, 2024, we sold an aggregate of 492,855 shares of common stock under the 2023 ATM Facility, at an average price of \$19.23 per share, for gross proceeds of \$9.5 million and net proceeds of \$9.3 million, after deducting commissions and other offering expenses payable by us.

As of December 31, 2024, we had \$88.7 million of common stock remaining and available to be sold under the 2023 ATM Facility.

Equity Incentive Plans

In June 2024, we adopted the 2024 Equity Incentive Plan (the 2024 EIP), under which we may grant stock options, restricted stock awards (RSAs) and RSUs to employees, directors, consultants and other service providers. RSUs generally vest over two to four years. The 2014 Equity Incentive Plan, as amended (the 2014 EIP), expired March 31, 2024, after which no new awards can be granted from it. All awards granted prior to the 2014 EIP expiration continue to remain outstanding and governed in accordance with the rules set forth in the 2014 EIP and the terms of the associated grant notice. To the extent forfeited, cancelled or expired, certain awards granted under the 2014 EIP will become available for grant under the 2024 EIP.

RSUs generally vest over two to four years. We have granted performance-based RSUs to certain of our employees that provide for the issuance of common stock if specified Company performance criteria related to tab-cel regulatory milestones are achieved. The number of performance-based RSUs that ultimately vests depends upon if and which performance criteria are achieved, as well as the employee's continuous service, as defined in the 2014 EIP and 2024 EIP, through the date of vesting. The fair value of performance-based RSUs is determined as the closing stock price on the date of grant.

Stock options are granted at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an option granted to a 10% shareholder cannot be less than 110% of the estimated fair value of the shares on the date of grant. Options granted generally vest over three to four years and expire in seven to ten years.

We have granted performance-based stock options to certain of our employees that provide for the issuance of a right to purchase a share of common stock if specified Company performance criteria related to tab-cel regulatory milestones are achieved. The vesting of performance-based stock options depends upon if and when the performance criteria are achieved, as well as the employee's continuous service, as defined in the 2014 EIP and 2024 EIP, through the date of vesting.

As of December 31, 2024, a total of 554,974 shares of common stock were reserved for issuance under the 2014 EIP, of which all were subject to outstanding options and RSUs, including performance-based awards.

As of December 31, 2024, a total of 392,571 shares of common stock were reserved for issuance under the 2024 EIP, of which 347,571 shares were available for future grant and 45,000 shares were subject to outstanding options and RSUs.

In February 2018, we adopted the 2018 Inducement Plan (Inducement Plan), under which we may grant options, stock appreciation rights, RSAs and RSUs to new employees. In November 2020, September 2021 and June 2022, we amended the Inducement Plan to reserve an additional 60,000 shares of the Company's common stock for issuance under the Inducement Plan in each case.

As of December 31, 2024, 170,873 shares of common stock were reserved for issuance under the Inducement Plan, of which 122,234 shares were available for future grant and 48,639 shares were subject to outstanding options and RSUs.

Restricted Stock Units

The following is a summary of RSU activity under our 2014 EIP, 2024 EIP and Inducement Plan:

	RSUs	
	Shares	Weighted Average Grant Date Fair Value
Balance as of December 31, 2023	250,709	\$ 158.00
Granted	548,990	\$ 13.76
Forfeited	(70,120)	\$ 86.29
Vested	(315,109)	\$ 79.06
Balance as of December 31, 2024	<u>414,470</u>	\$ 39.09

The weighted average grant date fair value of RSUs granted during the years ended December 31, 2024 and 2023 was \$13.76 and \$89.25, respectively. The estimated fair value of RSUs that vested in the years ended December 31, 2024 and 2023 was \$24.9 million and \$32.8 million, respectively. As of December 31, 2024, there was \$14.0 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 1.4 years. The aggregate intrinsic value of the RSUs outstanding as of December 31, 2024 was \$5.5 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 2024, we settled 315,109 shares underlying RSUs, of which 987 shares underlying RSUs were net settled by withholding 366 shares. The value of the shares underlying RSUs withheld was not material, based on the closing price of our common stock on the settlement date. During 2023, we settled 147,520 shares underlying RSUs, of which 2,050 shares underlying RSUs were net settled by withholding 728 shares. The value of the shares underlying RSUs withheld was \$0.1 million, based on the closing price of our common stock on the settlement date. The value of RSUs withheld in each period was remitted to the appropriate taxing authorities and has been reflected as a financing activity in our consolidated statements of cash flows.

Stock Options

The following is a summary of stock option activity under our 2014 EIP, 2024 EIP and Inducement Plan:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2023	428,786	\$ 290.75	6.5	\$ —
Granted	16,500	11.00		
Exercised	—	—		
Forfeited or expired	(211,143)	349.66		
Balance as of December 31, 2024	<u>234,143</u>	\$ 217.91	7.0	\$ 27
Vested and expected to vest as of				
December 31, 2024	234,143	\$ 217.91	7.0	\$ 27
Exercisable as of December 31, 2024	172,546	\$ 252.41	6.7	\$ 9

Aggregate intrinsic value represents the difference between the closing stock price of our common stock on December 31, 2024 and the exercise price of outstanding, in-the-money options. As of December 31, 2024, there was \$4.7 million of unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 1.0 years. This excludes unrecognized stock-based compensation expense for performance-based stock options that were deemed not probable of vesting in accordance with U.S. GAAP.

No options for shares of our common stock were exercised during the years ended December 31, 2024 and 2023. 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,	
	2024	2023
Assumptions:		
Expected term (years)	5.5	5.8
Expected volatility	114.2 %	83.9 %
Risk-free interest rate	4.0 %	4.2 %
Expected dividend yield	0.0 %	0.0 %
Fair Value:		
Weighted-average estimated grant date fair value per share	\$ 9.20	\$ 65.50
Options granted	16,500	187,756
Total estimated grant date fair value	<u>\$ 151,800</u>	<u>\$ 12,298,010</u>

The estimated fair value of stock options that vested in the years ended December 31, 2024 and 2023 was \$9.0 million and \$17.0 million, respectively.

Employee Stock Purchase Plan

In May 2014, we adopted the 2014 Employee Stock Purchase Plan ("2014 ESPP"), which became effective on October 15, 2014 upon the pricing of our IPO. Following stockholder approval, in June 2024, we amended the 2014 ESPP to increase the number of shares of our common stock available for issuance under the 2014 ESPP by 40,000 shares. The 2014 ESPP permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. Eligible employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the common stock at (i) the beginning of the offering period or (ii) at the end of the purchase period. We recorded \$0.2 million and \$0.7 million of expense related to the 2014 ESPP in the years ended December 31, 2024 and 2023, respectively. A total of 25,897 and 35,850 shares were purchased under the ESPP during the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, there was \$0.1 million of unrecognized stock-based compensation expense related to the ESPP that is expected to be recognized by the end of second quarter of 2025. As of December 31, 2024, there were 23,731 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, 2024:

	Total Shares Reserved
2014 Equity Incentive Plan	554,974
2018 Inducement Plan	170,873
2024 Equity Incentive Plan	392,571
2014 Employee Stock Purchase Plan	23,731
Total reserved shares of common stock	<u>1,142,149</u>

Stock-based Compensation Expense

The following is a summary of stock-based compensation expense for the periods presented:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Research and development	\$ 13,465	\$ 26,529
General and administrative	13,536	18,857
Total stock-based compensation expense	<u>\$ 27,001</u>	<u>\$ 45,386</u>

11. Income Taxes

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
United States	\$ (85,311)	\$ (276,360)
Foreign	(104)	249
Total loss before provision for income taxes	<u>\$ (85,415)</u>	<u>\$ (276,111)</u>

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Current provision for income taxes:		
State	\$ —	\$ 1
Foreign	(12)	14
Total current provision for income taxes	<u>\$ (12)</u>	<u>\$ 15</u>

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

	Year Ended December 31,	
	2024	2023
Federal income taxes at statutory rate	21.0 %	21.0 %
Research tax credits	(26.8 %)	4.3 %
Stock-based compensation	(16.2 %)	(4.5 %)
Other	(1.3 %)	(0.4 %)
Change in valuation allowance	23.3 %	(20.4 %)
Effective tax rate	<u>0.0 %</u>	<u>0.0 %</u>

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,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 259,376	\$ 323,581
Capitalized research expenses	61,113	72,229
Tax credit carryforwards	8,216	30,580
Stock-based compensation	5,789	14,033
Deferred revenue	14,709	17,018
Operating lease liabilities	9,403	12,035
License fees	4,794	5,926
Other	13,748	11,187
Total deferred tax assets	377,148	486,589
Valuation allowance	(368,401)	(474,982)
Total deferred tax assets	8,747	11,607
Deferred tax liabilities:		
Operating lease assets	(8,747)	(11,607)
Total deferred tax liabilities	(8,747)	(11,607)
Net deferred tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

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, 2024. The study concluded that we have experienced ownership changes since inception with the most recent being on September 5, 2024. As a result of the ownership changes and imposed annual limitations on the amount of our tax attributes that may be utilized in a given period, should we generate taxable income, we have determined that we will have net operating losses and tax credits that will expire unutilized. We have reduced our net operating loss carryforwards and tax credit carryforwards in the above table as a result.

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 decreased by \$11.1 million for the year ended December 31, 2024 and increased by \$21.7 million for the year ended December 31, 2023, respectively. The current year decrease is a result of more amortization than the amount capitalized in the current year whereas the prior year increase was partially offset by amortization on research expenses capitalized in prior years.

Our tax credit carryforwards decreased by \$22.4 million, as compared to 2023, due the Section 382 study limiting our ability to utilize attributes as a result of our ownership changes.

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, 2024 and 2023. 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 decreased by \$106.6 million for the year ended December 31, 2024 due to the decrease in our net deferred tax assets.

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. No changes have been made to our financial statements as of December 31, 2024.

Under the Tax Act, federal NOLs generated in tax years beginning on or after January 1, 2018 may be carried forward indefinitely, but the utilization of such federal NOLs is limited to 80% of taxable income in future years. Since enactment, the IRS and Treasury have issued final and proposed regulations including clarifying guidance on several topics addressed by the Tax Act. Not all states conform to the Tax Act or and other states have varying conformity to the Tax Act.

As of December 31, 2024, for federal income tax purposes, we had net operating loss carryforwards of approximately \$1.2 billion of which \$15.4 million begin to expire in 2036 and the remaining may be carried forward indefinitely, and research & development tax credits of \$1.1 million which begin to expire in 2044. For state income tax purposes, we had net operating loss carryforwards of approximately \$53.9 million which begin to expire in 2030, and research & development tax credits of \$45.8 million which may be carried forward indefinitely.

The changes in the balance of gross unrecognized tax benefits, which excludes interest and penalties, for the years ended December 31, 2023 and 2024 are as follows:

	(In thousands)
Balance as of January 1, 2023	150,965
Gross increases for tax positions related to current year	5,538
Gross increases for tax positions related to prior year	3,843
Gross decreases for tax positions related to prior year	—
Balance as of December 31, 2023	160,346
Gross increases for tax positions related to current year	1,011
Gross increases for tax positions related to prior year	647
Gross decreases for tax positions related to prior year	(124,071)
Balance as of December 31, 2024	<u>\$ 37,933</u>

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, 2024 and 2023 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, 2024, we are not permanently reinvested with respect to its foreign earnings and have not recorded deferred income taxes and withholding taxes as these taxes are immaterial to the financial statements.

12. Supplemental Balance Sheet Information

Inventories

Inventories consist of the following as of each period:

	December 31, 2024	December 31, 2023
	(in thousands)	
Raw Materials	\$ 964	\$ 2,335
Work-in-process	9,691	7,371
Total inventories	<u>\$ 10,655</u>	<u>\$ 9,706</u>

Property and equipment, net

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

	December 31, 2024	December 31, 2023
	(in thousands)	
Leasehold improvements	\$ 930	\$ 904
Lab equipment	14,446	15,540
Machinery and equipment	572	572
Computer equipment and software	1,381	1,279
Furniture and fixtures	1,272	1,272
Construction in progress	—	158
Property and equipment, gross	18,601	19,725
Less: accumulated depreciation	(17,307)	(15,869)
Property and equipment, net	<u>\$ 1,294</u>	<u>\$ 3,856</u>

Depreciation expense was \$2.7 million and \$3.7 million for the years ended December 31, 2024 and 2023, respectively.

Other current liabilities

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

	December 31, 2024	December 31, 2023
	(in thousands)	
Accrued operating expenses	\$ 6,027	\$ 19,007
Current portion of operating lease liabilities	12,879	11,264
Current portion of finance lease liabilities	1,038	915
Other accrued liabilities	598	640
Total other current liabilities	<u>\$ 20,542</u>	<u>\$ 31,826</u>

13.Subsequent Events

In January 2025, we announced a reduction in force of approximately 50% of total workforce. We expect to recognize approximately \$7.5 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2025. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from April 2025 to May 2026. The majority of the associated costs represent cash expenditures.

In March 2025, we announced a further reduction in force of approximately 50% of total workforce, retaining approximately 35 employees essential to executing on our strategic priorities. We expect to recognize approximately \$3.0 million in total severance and related benefits as a result of this reduction in force, consisting primarily of severance payments and wages for the 60-day notice period in accordance with the California WARN Act. In most cases, the severance will be paid in the first half of 2025. Certain of the notified employees had employment agreements which provided for separation benefits in the form of salary continuation; these benefits will be paid from May 2025 to May 2026. The majority of the associated costs represent cash expenditures.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2024. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer and Chief Operating Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2024 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 and Chief Operating Officer, as appropriate to allow timely discussion regarding required disclosures. In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024 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, 2024.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and Chief Financial Officer and Chief Operating 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 and Chief Operating Officer have concluded that, as of December 31, 2024, 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, 2024 which were identified in connection with our evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that many of our employees are working remotely. We are continually monitoring and assessing our remote working situation to minimize the impact to the design and operating effectiveness of our internal controls.

Item 9B. Other Information

During the three months ended December 31, 2024, none of the Company's directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934, as amended.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not Applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2025 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, 2024, and certain information to be included in the Definitive Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

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

We adopted an Insider Trading and Window Period Policy that governs the purchase, sale and other dispositions of its securities by our directors, officers and employees. We believe the Insider Trading and Window Period Policy is reasonably designed to promote compliance with insider trading laws, rules, and regulations, and any listing standards applicable to us. A copy of our Insider Trading and Window Period Policy is filed as Exhibit 19.1 to this Annual Report.

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	Form	Incorporated by Reference		Filed Herewith
			Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	3.2	06/20/2014	
3.2	Third Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	8-K	3.1	12/23/2024	
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	Form of September 2024 Pre-Funded Warrant	8-K	4.1	09/03/2024	
4.6	Description of Securities				X
10.1*	Amended and Restated 2014 Equity Incentive Plan	10-Q	10.2	08/08/2016	
10.2*	Forms of Option Agreement and Option Grant Notice under the 2014 Equity Incentive Plan	S-1	10.2	06/20/2014	
10.3*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice	10-Q	10.2	11/01/2023	
10.4*	2014 Employee Stock Purchase Plan	S-1/A	10.8	07/10/2014	
10.5*	Atara Biotherapeutics, Inc. Third Amended and Restated 2018 Inducement Plan	S-8	4.3	07/22/2022	
10.6*	Form of Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the Inducement Plan	10-Q	10.2	11/07/2019	
10.7*	Form of Stock Option Agreement and Stock Option Grant Notice under the Inducement Plan	10-Q	10.3	05/08/2018	
10.8*	Forms of Inducement Grant Notice and Inducement Grant Agreement	10-Q	10.3	08/07/2017	
10.9*	Form of Indemnification Agreement made by and between Atara Biotherapeutics, Inc. and each of its directors and executive officers	S-1	10.9	06/20/2014	
10.10*	Form of Atara Biotherapeutics, Inc. Executive Employment Agreement	10-K	10.39	02/28/2022	
10.11*	Executive Employment Agreement, dated May 23, 2019, by and between Pascal Touchon and Atara Biotherapeutics, Inc.	8-K	10.1	05/28/2019	
10.12†	Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of June 12, 2015	S-1	10.30	06/29/2015	
10.13†	Amendment No. 1 to the Exclusive License Agreement, by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated as of August 30, 2018	10-K	10.14	02/26/2019	
10.14	Office Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated as of December 9, 2015	10-K	10.29	03/04/2016	
10.15	First Amendment to Lease, by and between BXP 611 Gateway Center LP and Atara Biotherapeutics, Inc., dated October 21, 2020	10-Q	10.4	11/09/2020	
10.16	Second Amendment to Lease, by and between Atara Biotherapeutics, Inc. and 611 Gateway Center LP, LLC, dated December 9, 2021	10-K	10.36	02/28/2022	

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		Filed Herewith
			Exhibit	Filing Date	
10.17	Standard Industrial Lease by and between Thousand Oaks Industrial Portfolio, LLC and Atara Biotherapeutics, Inc. dated February 6, 2017	10-Q	10.1	05/04/2017	
10.18	Lease Agreement between LA Region No. 2, LLC and Atara Biotherapeutics, Inc. dated March 17, 2021	10-Q	10.2	05/04/2021	
10.19	First Amended and Restated Exclusive License Agreement by and between Atara Biotherapeutics, Inc. and Memorial Sloan Kettering Cancer Center, dated March 22, 2021	10-Q	10.3	05/04/2021	
10.20	Fourth Amended and Restated Research and Development Collaboration Agreement between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated December 17, 2021	10-K	10.37	02/28/2022	
10.21	Fourth Amended and Restated Exclusive License Agreement between Atara Biotherapeutics, Inc. and the Counsel of the Queensland Institute of Medical Research, dated December 17, 2021	10-K	10.38	02/28/2022	
10.22	Asset Purchase Agreement, dated as of January 26, 2022, by and between Atara Biotherapeutics, Inc., FUJIFILM Diosynth Biotechnologies California, Inc., and certain limited purposes, FUJIFILM Holdings America Corporation	8-K	2.1	04/04/2022	
10.23	Master Services and Supply Agreement dated as of January 26, 2022 by and between Atara Biotherapeutics, Inc., and FUJIFILM Diosynth Biotechnologies California, Inc.	10-Q	10.1	05/05/2022	
10.24+	Purchase and Sale Agreement between Atara Biotherapeutics, Inc., and HCR Molag Fund, L.P., dated December 20, 2022	10-K	10.46	02/08/2023	
10.25	Amendment No. 2 to Commercial Manufacturing Services Agreement dated as of May 31, 2022 by and between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc.	10-Q	10.1	08/08/2022	
10.26+	Amendment No. 3 to Commercial Manufacturing Services Agreement dated as of August 1, 2022 by and between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc.	10-Q	10.1	11/08/2022	
10.27+	Amendment No. 4 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated January 30, 2023	10-Q	10.1	05/08/2023	
10.28+	Amendment No. 5 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated September 27, 2023	10-Q	10.1	11/01/2023	
10.29+	Amendment No. 6 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated December 30, 2023	10-K	10.29	03/28/2024	
10.30+	Amendment No. 7 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, Inc. and Charles River Laboratories, Inc. dated January 31, 2024	10-K	10.30	03/28/2024	
10.31+	Amendment No. 8 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, In. and Charles River Laboratories, Inc. dated March 31, 2024	10-Q	10.1	05/09/2024	
10.32+	Amendment No. 9 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, In. and Charles River Laboratories, Inc. dated April 30, 2024	10-Q	10.1	08/12/2024	

Exhibit Number	Exhibit Description	Form	Incorporated by Reference		Filed Herewith
			Exhibit	Filing Date	
10.33+	Amendment No. 10 to Commercial Manufacturing Services Agreement between Atara Biotherapeutics, In. and Charles River Laboratories, Inc. dated May 31, 2024	10-Q	10.2	08/12/2024	
10.34+	Amended and Restated Commercialization Agreement by and between Atara Biotherapeutics, Inc. and Pierre Fabre Medicament dated October 31, 2023	10-K	10.31	03/28/2024	
10.35*	Atara Biotherapeutics, Inc. 2024 Equity Incentive Plan	S-8	4.4	6/11/2024	
19.1	Insider Trading and Window Period Policy				X
21.1	List of Subsidiaries				X
23.1	Consent of Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (included on signature page)				
31.1	Certification of the Chief Executive Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of the Chief Financial Officer pursuant to Rules 13A-14A and 15D-14A of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
97.1	Incentive Compensation Recoupment Policy				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document) and contained in Exhibit 101)				X

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

+ Certain confidential information contained in this exhibit has been omitted because it is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

* Indicates management contract or compensatory plan or arrangement.

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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Thousand Oaks, State of California, on the 7th day of March, 2025.

Atara Biotherapeutics, Inc.

By: /s/ AnhCo Thieu Nguyen
AnhCo Thieu Nguyen
President and Chief Executive Officer

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

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

Signature	Title	Date
/s/ AnhCo Thieu Nguyen AnhCo Thieu Nguyen	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 7, 2025
/s/ Eric Hyllengren Eric Hyllengren	Chief Financial Officer and Chief Operating Officer <i>(Duly Authorized Officer and Principal Financial and Accounting Officer)</i>	March 7, 2025
/s/ Pascal Touchon Pascal Touchon, D.V.M.	Director, Chair	March 7, 2025
/s/ Carol G. Gallagher Carol G. Gallagher, Pharm. D.	Lead Director	March 7, 2025
/s/ Matthew K. Fust Matthew K. Fust	Director	March 7, 2025
/s/ William K. Heiden William K. Heiden	Director	March 7, 2025
/s/ Ameet Mallik Ameet Mallik	Director	March 7, 2025
/s/ Maria Grazia Roncarolo Maria Grazia Roncarolo, M.D.	Director	March 7, 2025
/s/ Gregory Ciongoli Gregory Ciongoli	Director	March 7, 2025

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

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

DESCRIPTION OF CAPITAL STOCK

General

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

Our authorized capital stock consists of 520,000,000 shares, all with a par value of \$0.0001 per share, of which 500,000,000 shares are designated as common stock and 20,000,000 shares are designated as preferred stock.

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

Common Stock

Voting Rights

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

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

Economic Rights

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

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

Rights and preferences. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully paid and nonassessable. All of our outstanding shares of our common stock, par value \$0.0001 per share, are fully paid and nonassessable.

Preferred Stock

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

Warrants

As part of our July 2019 underwritten public offering, we issued and sold pre-funded warrants to purchase 117,801 shares of common stock in an underwritten public offering pursuant to a shelf registration on Form S-3.

Each of the July 2019 pre-funded warrants issued entitles the holder to purchase one share of common stock at an exercise price of \$0.0025 per share and expires seven years from the date of issuance. These warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise (the "July 2019 Warrant Maximum Ownership Percentage"). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the July 2019 Warrant Maximum Ownership Percentage to any other percentage not to exceed 19.99%. No July 2019 pre-funded warrants were exercised during the year ended December 31, 2024, and, as of December 31, 2024, pre-funded warrants to purchase 101,089 shares of our common stock from the July 2019 underwritten public offering were outstanding.

As part of the May 2020 underwritten public offering, we issued and sold pre-funded warrants to purchase 114,678 shares of common stock in an underwritten public offering pursuant to a shelf registration on Form S-3.

Additionally, as part of the December 2020 underwritten public offering, we issued and sold pre-funded warrants to purchase 81,632 shares of common stock in an underwritten public offering pursuant to a shelf registration on Form S-3. These warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital.

The terms of the pre-funded warrants issued and sold as part of the May 2020 and December 2020 public offerings were similar to those issued and sold in July 2019. No May 2020 or December 2020 pre-funded warrants were exercised during the year ended December 31, 2024. As of December 31, 2024, 38,735 shares and 55,387 shares of the May 2020 and December 2020 pre-funded warrants to purchase shares of our common stock issued and sold as part of the May 2020 and December 2020 underwritten public offerings, respectively, were outstanding.

In January 2024, we issued and sold pre-funded warrants to purchase 1,090,907 shares of common stock at a price of \$13.7475 per warrant in a registered direct offering pursuant to a shelf registration on Form S-3. The gross proceeds from this sale were \$15.0 million, resulting in net proceeds of \$14.8 million after deducting offering expenses payable by us.

Each of the January 2024 pre-funded warrants issued entitles the holder to purchase one share of common stock at an exercise price of \$0.0025 per share, with no expiration date. These warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital. Per the terms of the warrant agreement, a holder of the outstanding warrants is not entitled to exercise any portion of any pre-funded warrant if, upon exercise of the warrant, the holder's ownership (together with its affiliates) of our common stock or combined voting power of our securities beneficially owned by such holder (together with its affiliates) would exceed 9.99% after giving effect to the exercise (the "January 2024 Maximum Ownership Percentage"). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the January 2024 Maximum Ownership Percentage to any other percentage not to exceed 19.99%. No January 2024 pre-funded warrants were exercised during the year ended December 31, 2024 and all 1,090,907 of the January 2024 pre-funded warrants remained outstanding as of December 31, 2024.

In September 2024, we issued and sold 758,900 shares of common stock at an offering price of \$8.25 per share and pre-funded warrants to purchase 3,604,780 shares of common stock at a price of \$8.2499 per warrant in a registered direct offering pursuant to a shelf registration on Form S-3. The gross proceeds from this sale were \$36.0 million, resulting in net proceeds of \$35.8 million after deducting offering expenses payable by us.

Each of the September 2024 pre-funded warrants issued entitles the holder to purchase one share of common stock at an exercise price of \$0.0001 per share, with no expiration date. These warrants were recorded as a component of stockholders' equity (deficit) 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, at the holder's election, 4.99%, 9.99% or 19.99% after giving effect to the exercise (the "September 2024 Warrant Maximum Ownership Percentage"). Upon at least 61 days' prior notice to us by the holder, any holder may increase or decrease the September 2024 Warrant Maximum Ownership Percentage to any other percentage not to exceed 19.99%.

During the year ended December 31, 2024, 8,634 shares of the September 2024 pre-funded warrants were exercised, and as of December 31, 2024, the September 2024 pre-funded warrants to purchase 3,596,146 shares of our common stock from the September 2024 direct offering were outstanding.

Anti-Takeover Provisions

Anti-Takeover Statute

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

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

In general, Section 203 defines business combination to include the following:

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

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

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

Anti-Takeover Effects of Certain Provisions of our Amended and Restated Certificate of Incorporation, as amended, and Third Amended and Restated Bylaws

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

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

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

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

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

Choice of Forum

Our third amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the 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 of our current or former director, officer, or other employee 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 or any director or officer or other employee of 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 foregoing provisions do not apply to any claims arising under the Securities Act of 1933, as amended (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..

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar’s address is 150 Royall Street, Canton, Massachusetts 02021.

Listing on the Nasdaq Global Select Market

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

ATARA BIOTHERAPEUTICS, INC.
INSIDER TRADING AND WINDOW POLICY
(JANUARY 8, 2025)

INTRODUCTION

During the course of your relationship with Atara Biotherapeutics, Inc. (“**Atara**”), you may receive material information that is not yet publicly available (“**material nonpublic information**”) about Atara. Material nonpublic information may give you or someone you pass that information on to a leg up over others when deciding whether to buy, sell or otherwise deal in Atara’s securities or the securities of another publicly traded company. This policy sets forth acceptable transactions in Atara securities by our employees, directors and consultants.

INSIDER TRADING POLICY***Securities Transactions***

Using material nonpublic information for personal gain or passing this information (also known as a “**tip**”) to someone who uses it for personal gain (a “**tippee**”) is illegal and prohibited by this policy. Exploiting material nonpublic information like this remains unlawful regardless of how many shares are bought or sold. You can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee’s tippee.

From time to time, Atara may engage in transactions in Atara’s securities. It is Atara’s policy to comply with all applicable federal and state securities laws or stock exchange listing standards when engaging in transactions in Atara’s securities.

Material nonpublic information

Information is material if it might be of significance to an investor, as part of the total mix of available information, in determining whether to purchase, sell or hold a company’s securities. Information may be significant for this purpose even if it would not alone determine the investor’s decision. Keep in mind that both positive and negative information can be material. “Nonpublic” information is any information that has not yet been disclosed generally to the marketplace. Information received about a company under circumstances that indicate that it is not yet in general circulation should be considered nonpublic.

Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed. There may be other types of information that would qualify as material nonpublic information as well:

- financial results or forecasts;
 - status of product or product candidate development or regulatory approvals;
 - clinical data relating to products or product candidates;
 - timelines for pre-clinical studies or clinical trials;
 - acquisitions or dispositions of assets, divisions or companies;
 - public or private sales of debt or equity securities;
 - stock splits, dividends or changes in dividend policy;
 - gain or loss of a significant licensor, licensee or supplier;
 - changes or new corporate partner relationships or collaborations.
-

- notice of issuance or denial of patents;
- regulatory developments;
- management or control changes;
- employee layoffs;
- a disruption in the company's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- litigation or settlements; and
- impending bankruptcy.

If you do possess material nonpublic information, you may not trade in a company's securities or advise anyone else whether to do so. In addition, if you possess material nonpublic information, you may not communicate the information to anyone else (other than employees whose job responsibilities require the information and who are bound by this policy) until you know that the information has been widely publicly disseminated and sufficient time (at least one full trading day) has passed to allow securities markets to receive and evaluate the information.

"Trading" includes not only purchases, sales and gifts of common stock in the public market but also any other purchases, sales, gifts or transfers of common or preferred equity, options, warrants and other securities (including debt securities and distributions of securities by an investment fund to its equity holders) and other arrangements that affect economic exposure to changes in the prices of these securities.

WHO IS COVERED BY THIS POLICY

This policy applies to employees, directors, consultants, contractors of Atara (which includes its subsidiaries) and their family members and entities whose transactions in securities you influence, direct or control (including, for example, a venture or other investment fund, if you influence, direct or control transactions by the fund). For purposes of this policy, a "family member" includes a person's spouse, parents, children, siblings, mothers and fathers-in-law, sons and daughters-in-law, brothers and sisters-in-law, and anyone (other than domestic employees) who shares such person's home. You are responsible for making sure that these other individuals and entities comply with this policy. However, this insider trading policy does not apply to any such entity that invests in securities in the ordinary course of its business (e.g., an investment fund or partnership) if such entity has established its own insider trading controls and procedures in compliance with applicable securities laws.

Open Window - Generally

Because our workplace culture tends to be open, odds are that the vast majority of our employees, directors and consultants will either possess or have access to material nonpublic information at certain points during the year. To minimize even the appearance of insider trading by our employees, directors and consultants, we have established trading blackout periods. That means that anyone covered by this policy will be able to sell Atara securities only during limited trading windows that open after Atara has disseminated its quarterly and annual financial results.

Except as described in this policy, anyone covered by this policy may buy or sell Atara securities only during an **"open window."** Generally, the window will open after one full trading day has elapsed since the public dissemination of Atara's annual or quarterly financial results and close on the 15th of the third month of each quarter (for example, the window would close on

September 15 for the quarter ending September 30 and on December 15 for the quarter ending December 31).

Event-Specific Closed Window

From time to time, an event may occur that is material to Atara and is known by only a limited number of directors, consultants and/or employees. In addition, Atara's financial results may be sufficiently material in a particular fiscal period that all employees, directors and consultants should not trade in the Atara's securities. In these circumstances, the window may be closed early or may not open at all for all employees, directors and consultants or for certain individuals designated by Atara. In that situation, upon prior notice to the persons affected and without disclosing the reason for the restriction, Atara may impose event-specific closed windows during which the designated individuals cannot trade in Atara's securities. The fact that the open window has closed early or has not opened should be considered material nonpublic information and should not be communicated to any other person.

An employee, director or consultant who believes that special circumstances require them to trade outside the open window should consult the General Counsel. Permission to trade outside the open window will be granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may subsequently be questioned.

Exceptions

1. Option Exercises and RSU Net Settlement. Employees, directors and consultants may (i) exercise options granted under Atara's equity incentive plans for cash or, where permitted under the option, by net exercise and (ii) net settle restricted stock units ("**RSUs**") and have Atara withhold shares to satisfy tax withholding obligations arising in connection with the RSUs settlement. But this insider trading policy would then apply to any later sales or gifts of stock (including sales or gifts of stock in a broker assisted cashless exercise) that were acquired on the exercise of options or delivery of the vested RSUs.

2. ESPP Purchases. Individuals who are eligible to do so may purchase stock under Atara's Employee Stock Purchase Plan ("**ESPP**") on periodic designated dates in accordance with the ESPP without restriction to any particular period. However, the subsequent sale or gift of the stock acquired pursuant to the ESPP is subject to all provisions of this policy.

3. 10b5-1 Automatic Trading Programs. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("**Exchange Act**"), employees, directors and consultants may establish a trading plan under which a broker is instructed to buy and sell Atara securities based on pre-determined criteria (a "**Trading Plan**"). So long as a Trading Plan is properly established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Atara, purchases, sales and gifts of Atara securities pursuant to that plan may be made at any time pursuant to the pre-determined criteria—even in a trading blackout period. An employee's, director's or consultant's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Atara at a time when they lacked material nonpublic information about Atara and when Atara was not in a trading blackout period. Moreover, all Trading Plans must be reviewed by Atara before being established to confirm that the Trading Plan complies with all pertinent company policies and the securities laws. Atara must be notified before a Trading Plan is established, amended or terminated.

Prohibition of Speculative or Short-term Trading

Short sales, transactions in put or call options, hedging transactions, margin accounts, pledges or other inherently speculative transactions with respect to Atara's stock are prohibited.

Pre-Clearance and Advance Notice of Transactions

In addition to the requirements above, all directors, Section 16 officers and any other employee who has been notified that they are subject to pre-clearance requirements face a further restriction. Even during an open trading window, they may not engage in any transaction in Atara's securities, including any purchase or sale in the open market, gift, loan or other transfer of beneficial ownership without first obtaining pre-clearance of the transaction from Atara's General Counsel or his or her designee at least 48 hours before the proposed transaction. Persons subject to pre-clearance must also give advance notice of gifts or plans to exercise an outstanding stock option to the General Counsel. If a proposed transaction receives pre-clearance, the pre-cleared trade must be effected within three (3) trading days of receipt of pre-clearance. If the person becomes aware of material nonpublic information before the trade is executed, the pre-clearance is void and the trade must not be completed.

POLICY'S DURATION

This policy applies to your transactions in Atara's securities, as well as the securities of other public companies that are (1) engaged in business transactions with Atara or (2) involved in a potential business transaction with Atara, where you are in possession of material nonpublic information about that company that was obtained in your capacity as an employee, director or consultant of Atara. This policy continues to apply to your transactions in Atara's securities or the securities of such other public companies even after your employment or directorship with the Company has terminated. If you possess material nonpublic information when your relationship with Atara ends, you may not trade Atara's securities or the securities of such other companies until the material nonpublic information has been publicly disseminated or is no longer material.

PENALTIES

Anyone who engages in insider trading or otherwise violates this insider trading policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Atara, including termination. Anyone who has questions about this policy should contact their own attorney or Atara's General Counsel.

AMENDMENTS

Atara is committed to continuously reviewing and updating its policies and procedures. Atara therefore reserves the right to amend, alter or terminate this policy at any time and for any reason, subject to applicable law. A current copy of Atara's policies regarding insider trading may be obtained by contacting the General Counsel.

LIST OF SUBSIDIARIES

The following is a list of subsidiaries of the Company as of December 31, 2024:

Subsidiary Legal Name	State or other Jurisdiction of Incorporation or Organization
Atara Biotherapeutics Ireland Limited	Ireland
Atara Biotherapeutics Switzerland GmbH	Switzerland

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in registration statements No. 333-199508, No. 333-204076, No. 333-209961, No. 333-214431, No. 333-219763, No. 333-223254, No. 333-229861, No. 333-236704, No. 333-249976, No. 333-253734, No. 333-259882, No. 333-263109 No. 333-266288, No. 333-269647, No. 333-276360, No. 333-280125, No. 333-280126, and No. 333-284338 on Form S-8 and registration statement No. 333-275256 on Form S-3 of our report dated March 3, 2025, relating to the consolidated financial statements of Atara Biotherapeutics, Inc. and subsidiaries (the “Company”) appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2024.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
March 7, 2025

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

I, AnhCo Thieu Nguyen, certify that:

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

Date: March 7, 2025

/s/ AnhCo Thieu Nguyen
AnhCo Thieu Nguyen
President and Chief Executive Officer
(Principal Executive Officer)

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

I, Eric Hyllengren, certify that:

1. I have reviewed this Annual Report on Form 10-K of Atara Biotherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2025

/s/ Eric Hyllengren
Eric Hyllengren
Chief Financial Officer and Chief Operating 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, 2024, as filed with the Securities and Exchange Commission (the "Report"), AnhCo Thieu Nguyen, Chief Executive Officer of the Company, and Eric Hyllengren, Chief Financial Officer and Chief Operating Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 7, 2025

/s/ AnhCo Thieu Nguyen
AnhCo Thieu Nguyen
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Eric Hyllengren
Eric Hyllengren
Chief Financial Officer and Chief Operating 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.

ATARA BIOTHERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the “**Board**”) of Atara Biotherapeutics, Inc. (the “**Company**”) has determined that it is in the best interests of the Company to adopt this Incentive Compensation Recoupment Policy (this “**Policy**”) providing for the Company’s recoupment of certain Incentive Compensation (as defined below) paid to Covered Officers (as defined below) of the Company under certain circumstances in the event of a restatement of financial results by the Company. The Board may delegate determinations to be made under this Policy to a committee of the Board (the “**Committee**”), and the Board and any such authorized Committee are collectively referred to in this Policy as the “**Board**.”

This Policy shall be interpreted to comply with the requirements of U.S. Securities and Exchange Commission (“**SEC**”) rules and Nasdaq Stock Market (“**Nasdaq**”) listing standards implementing Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the “**Dodd-Frank Act**”) and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

This Policy shall be administered by the Board and, except as specifically provided herein and to the extent consistent with the rules and listing standards implementing Section 954 of the Dodd-Frank Act, the Board shall have full and final authority to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the Dodd-Frank Act. Any determination by the Board with respect to this Policy shall be final, conclusive and binding on all interested parties, including all Covered Officers and their beneficiaries, executors, administrators, and other legal representatives. The Board may amend or terminate this Policy at any time, subject to SEC rules and Nasdaq listing standards.

2. EFFECTIVE DATE

This Policy has been adopted by the Board on October 24, 2023, and shall apply to all Incentive Compensation paid or awarded on or after October 2, 2023.

3. DEFINITIONS

For purposes of this Policy, the following terms shall have the meanings set forth below:

“**Accounting Restatement**” means the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

“**Covered Officer**” means a current or former “executive officer” of the Company within the meaning of Rule 10D-1 under the Securities Exchange Act of 1934, as amended.

“**Incentive Compensation**” means any compensation that is granted, earned or vested based in whole or in part on the attainment of a financial reporting measure determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measure that is derived wholly or in part from such measures, whether or not presented within the Company’s financial

statements or included in a filing with the SEC, including stock price and total stockholder return (“*TSR*”), including but not limited to performance-based cash, stock, options or other equity-based awards paid or granted to the Covered Officer. Compensation that is granted, vests or is earned based solely upon the occurrence of non-financial events, such as base salary, restricted stock or options with time-based vesting, or a bonus awarded solely at the discretion of the Board and not based on the attainment of any financial measure, is not subject to this Policy. Incentive Compensation is considered to have been received by a Covered Officer in the fiscal year during which the applicable financial reporting measure was attained or purportedly attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

“*Recoverable Incentive Compensation*” means Incentive Compensation received during the Recovery Period.

“*Recovery Period*” means the three completed fiscal years immediately preceding the date on which the Company is required to prepare the Accounting Restatement, as determined in accordance with this definition, or any transition period that results from a change in the Company’s fiscal year (as set forth in Section 5608(b)(i)(D) of the Nasdaq Listing Rules). The date on which the Company is required to prepare an Accounting Restatement is the earlier to occur of (A) the date the Board or a Board committee (or authorized officers of the Company if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

4. RECOUPMENT

a. Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the amount to be recovered will be the excess of (i) the Recoverable Incentive Compensation received by the Covered Officer based on the erroneous data and calculated without regard to any taxes paid or withheld, over (ii) the Incentive Compensation that would have been received by the Covered Officers had it been calculated based on the restated financial information, as determined by the Board. For Incentive Compensation based on stock price or *TSR*, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Accounting Restatement, then the Board shall determine the amount to be recovered based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or *TSR* upon which the Incentive Compensation was received and the Company shall document the determination of that estimate and provide it to Nasdaq.

b. Sources of Recoupment. To the extent permitted by applicable law, the Board, in its discretion, may use any legal or equitable remedies that are available to the Company to seek recoupment from a Covered Officer, including but not limited to, recoupment from any of the following sources: direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; future payments of other Incentive Compensation; and cancellation of outstanding Incentive Compensation. To the extent permitted by applicable law, the Company may also offset the recoupment amount owed to the Company against any compensation or other amounts owed by the Company to the Covered Officer. Covered Officers shall be solely responsible for any tax consequences to them that result from the recoupment or recovery of any amount pursuant to this Policy, and the Company shall have no obligation to administer the Policy in a manner that avoids or minimizes any such tax consequences.

c. No-Fault Recovery. Recoupment under this Policy shall be required regardless of whether the Covered Officer or any other person was at fault or responsible for accounting errors that contributed to the need for the Accounting Restatement or engaged in any misconduct.

d. Exceptions. The compensation recouped under this Policy shall not include Incentive Compensation received by a Covered Officer (i) prior to beginning service as a Covered Officer or (ii) if he or she did not serve as a Covered Officer at any time during the performance period applicable to the Incentive Compensation in question. The Board may determine not to seek recovery from a Covered Officer in whole or part to the extent it determines in its sole discretion that such recovery would be impracticable because (A) the direct expense paid to a third party to assist in enforcing recovery would exceed the recoverable amount (after having made a reasonable attempt to recover the erroneously awarded Incentive Compensation and providing corresponding documentation of such attempt to Nasdaq), (B) recovery would violate the home country law that was adopted prior to November 28, 2022, as determined by an opinion of counsel licensed in the applicable jurisdiction that is acceptable to and provided to Nasdaq, or (C) recovery would likely cause the Company's 401(k) plan or any other tax-qualified retirement plan to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

5. SEVERABILITY

If any provision of this Policy or the application of any such provision to any Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

6. NO IMPAIRMENT OF OTHER REMEDIES

This Policy shall be without prejudice to any other rights or remedies that the Company, or the Board may have, and does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, whether arising under applicable law (including pursuant to Section 304 of the Sarbanes-Oxley Act of 2002), regulation or pursuant to the terms of any other policy of the Company, employment agreement, equity award, cash incentive award or other agreement applicable to a Covered Officer, including termination of employment, institution of civil proceedings, or reporting of any misconduct to appropriate government authorities. Notwithstanding the foregoing, there shall be no duplication of recovery of the same Incentive Compensation under this Policy and any other such rights or remedies.

7. NO INDEMNIFICATION

The Company shall not indemnify any Covered Officer or pay or reimburse the premium for any insurance policy to cover any losses incurred by such Covered Officer under this Policy or any claims relating to the Company's enforcement of rights under this Policy.

