

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-K**

**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 001-37368

**ADAPT IMMUNE THERAPEUTICS PLC**

(Exact name of Registrant as specified in its charter)

**England and Wales**

(State or other jurisdiction of incorporation or organization)

**Not Applicable**

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

**60 Jubilee Avenue, Milton Park  
Abingdon, Oxfordshire OX14 4RX  
United Kingdom**

(Address of principal executive offices)

**(44) 1235 430000**

(Registrant's telephone number, including area code)

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

**Title of each class**  
American Depositary Shares, each representing  
6 Ordinary Shares, par value £0.001 per share

**Trading Symbol(s)**  
ADAP

**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 Section 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 and post 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 the 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 Act).  Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$230,884,394.

As of March 21, 2025 the number of outstanding ordinary shares, par value £0.001 per share, of the registrant was 1,543,391,646.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement for the 2025 Annual Meeting of Shareholders to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

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## GENERAL INFORMATION

In this Annual Report on Form 10-K (“Annual Report”), “Adaptimmune,” the “Group,” the “Company,” “we,” “us” and “our” refer to Adaptimmune Therapeutics plc and its consolidated subsidiaries, except where the context otherwise requires. “Adaptimmune” is a registered trademark of Adaptimmune.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect” or the negative of these words or other comparable terminology.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and elsewhere in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

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## **PART I**

### **Item 1. Business**

#### **Overview**

We are a commercial-stage biopharmaceutical company working to redefine the treatment of solid tumor cancers with cell therapies. With the approval by the U.S. Food and Drug Administration (“FDA”) of our first biologics license application (“BLA”) for TECELRA® (afamitresgene autoleucel) (“TECELRA”), which is the first engineered T-cell therapy for the treatment of a solid tumor cancer approved in the U.S., we are now focused on its launch and commercialization.

TECELRA is a genetically modified autologous T-cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A\*02:01P, -A\*02:02P, -A\*02:03P, or -A\*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. This indication is approved under the FDA’s accelerated approval based on overall response rate (“ORR”) and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a confirmatory trial.

We are planning commercial launch for our second T-cell immunotherapy, letetresgene autoleucel (“lete-cel”), for people with synovial sarcoma and myxoid liposarcoma in 2026. This product will significantly expand our treatable patient population within our commercial sarcoma franchise with up to \$400 million annual peak combined US sales from TECELRA and lete-cel. We estimate that approximately 400 newly diagnosed patients per year are biomarker eligible for TECELRA, and an incremental 600 newly diagnosed synovial sarcoma and myxoid liposarcoma patients per year in the US will be biomarker eligible for lete-cel.

In addition to our commercial sarcoma franchise we remain committed to our collaboration with Galapagos which uses our uzatresgene autoleucel (“uza-cel”) candidate manufactured using the Galapagos manufacturing process. A clinical trial authorization to start a Phase 1 trial in head and neck cancer is planned for 2025.

All of our products and clinical candidates utilize engineered T-cells designed to find and destroy cancer cells in patients. The T-cells are engineered to recognize particular antigens expressed by the cancer cells and to activate a person’s immune system to fight the cancer they have. Our current products and clinical candidates are personalized treatment options where we take a person’s white blood cells, modify them to express the engineered T-cells and then return those engineered T-cells to the patient.

During the fourth quarter of 2024 we announced that we were ceasing further investment in all non-core programs. We are undertaking a reduction in headcount of approximately 29% and a reduction of total operating expenses of approximately 25% (as compared to 2024 operating expenses). As of the end of February 2025, the majority of the headcount reduction has been completed. As part of this restructuring in December 2024, we also announced changes to our executive leadership team. In addition, we are implementing additional cost reduction for our preclinical PRAME and CD70 programs and are evaluating all strategic options to maximize shareholder value.

#### ***TECELRA and Commercialization***

We are focused on the commercialization of TECELRA for the treatment of advanced synovial sarcoma and for which we received FDA approval on August 1, 2024. As of March 18, 2025, 20 Authorized Treatment Centers (“ATCs”) are available to initiate the treatment journey for our patients and ten patients have been apheresed. We are confident that our full network of approximately 30 ATCs will be active by the end of 2025, covering an estimated 80% of patients treated in sarcoma centers of excellence. Companion diagnostics for biomarker detection are approved and available and we have adequate manufacturing capacity to meet orders. AdaptimmuneAssist is available to support our patients and Health Care Providers (HCPs).

***Lete-cel***

Lete-cel targets the NY-ESO antigen and has been in clinical trials (the IGNUYTE-ESO trial) for people with synovial sarcoma and myxoid liposarcoma. It is the second product in our sarcoma franchise. Final data for the IGNUYTE-ESO trial were reported at the Connective Tissue Oncology Society Annual Meeting (“CTOS”) in November 2024.

In January 2025, lete-cel was granted breakthrough therapy designation by the U.S. FDA for the treatment of patients with unresectable or metastatic myxoid liposarcoma who have received prior anthracycline-based chemotherapy, are positive for HLA-A\*02:01, HLA-A\*02:05, or HLA-A\*02:06, and whose tumor expresses the NY-ESO-1 antigen.

***Clinical Programs***

During 2025 we anticipate filing an IND for ADP-5701 for a Phase 1 trial in Head and Neck Cancer in collaboration with Galapagos NV (“Galapagos”). The trial will utilize the uza-cel engineered T-cell Receptor (TCR) and Galapagos’ innovative decentralized cell therapy manufacturing platform. Uza-cel has shown encouraging results in head and neck cancer with partial responses in four out of five patients to date in a Phase 1 trial using Adaptimmune’s manufacturing platform.

***Pre-Clinical Programs***

We have two preclinical programs for the development of T-cell therapies directed to PRAME (ADP-600) and CD70 (ADP-520). We have implemented additional cost saving measures in relation to these programs.

***Collaborations***

We entered into a clinical collaboration agreement with Galapagos in May 2024. Under the collaboration agreement we will conduct a clinical proof-of-concept trial to evaluate the safety and efficacy of uza-cel produced on Galapagos’ decentralized manufacturing platform (ADP-5701) in patients with head and neck cancer.

Prior collaborations with Genentech, relating to the research of “off-the-shelf” cell therapies, and GSK, relating to the transition of the NY-ESO and PRAME programs, have now either terminated or been concluded.

***Corporate***

We have facilities in the U.S. in Philadelphia and Boston, and in the United Kingdom (“U.K.”).

During the fourth quarter of 2024 we announced that we were ceasing further investment in all non-core programs. We are undertaking a reduction in headcount of approximately 29% and a reduction of total operating expenses of approximately 25% (as compared to 2024 operating expenses). As of the end of February 2025, the majority of the headcount reduction has been completed. The restructuring aims to prioritize the commercial sarcoma franchise and R&D programs with the highest potential return on invested capital and transformational benefit to patients. As part of this restructuring the Company plans to focus an increasing proportion of its corporate functions in the US. We are also seeking strategic alternatives for our off-the shelf allogeneic cell therapy program. As part of this restructuring, we announced in December 2024 that Helen Tayton-Martin, our Co-founder and Chief Business and Strategy Officer, and Gavin Wood, our Chief Financial Officer, would step down on March 31, 2025 and May 31, 2025 respectively.

In addition to the restructuring announced in 2024, in March 2025 we announced implementation of additional cost reduction for the PRAME and CD70 programs. We are currently evaluating all strategic options for the Company and its programs.

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On March 24, 2025 we entered into an amendment to the Loan and Security Agreement dated May 14, 2024 with Hercules Capital, Inc. (“Loan Agreement”). Under the amendment we will pre-pay \$25 million of the loan amount under the Loan Agreement together with certain accrued interest up to the date of such pre-payment.

**Business Strategy**

Building on our leadership position with engineered T-cell therapies in solid tumor indications, our strategic objective is to be a world leader in designing, developing and delivering transformational cell therapies for the treatment of cancer. Our mission is to revolutionize the treatment of solid tumors with a single dose of engineered TCR T-cells and as a result to address cancers with high unmet needs. To achieve our mission, our primary core value drivers are as follows:

***Building a commercial franchise in synovial sarcoma and myxoid liposarcoma.*** Our first T-cell therapy product, TECELRA, is now approved in the US for the treatment of advanced MAGE-A4+ synovial sarcoma in adults with certain HLA types who have received prior chemotherapy. We will continue to increase the number of ATCs as quickly as possible during 2025 to maximise patient treatment with TECELRA within the US. We are intending to submit a rolling BLA for our second product, lete-cel starting in the US in 2025 and targeting U.S. commercial launch in 2026. We are also actively exploring the best way to expand the commercial franchise into other countries and/or into other HLA types.

***Progressing ADP-5701 (uza-cel manufactured on Galapagos manufacturing platform) into the clinic.*** We are collaborating with Galapagos to file a clinical trial authorization to bring ADP-5701 into the clinic during 2025.

***Continuing to improve our manufacturing and patient supply processes to optimize how we deliver our cell therapies to patients.*** Our cell therapy product manufacturing capabilities enable us to treat patients effectively and in support of our other priorities. We will continue to improve our manufacturing and patient supply processes and options using a mix of internal capabilities and external suppliers.

**Our Cell Therapies for Cancer**

***The Immune System and T-cells***

The immune system plays an important role in targeting and destroying cancer cells. Specifically, T-cells, which are a type of white blood cell, and their receptors create a natural system that is designed to scan the body for diseased cells. In general, cells process proteins internally and then convert these proteins into peptide fragments which are then presented on the cell surface by a protein complex called the Human Leukocyte Antigen (“HLA”). T-cells naturally scan all other cells in the body for the presence of abnormal peptide fragments, such as those generated from infectious agents. Recognition of this peptide-HLA complex takes place through the T-cell receptor or TCR expressed on the T-cells. However, binding of naturally occurring TCRs to cancer targets tends to be very poor because cancer proteins appear very similar to naturally occurring proteins on healthy cells.

***Cancer Target Identification and Validation***

Before developing any engineered T-cell therapy, it is important to identify and validate a suitable target cancer peptide or protein. The target or antigen must be expressed only on the cancer cells of interest or at very low expression levels in normal non-cancerous tissue. Careful validation and identification of targets is important to ensure that any engineered cell therapy is specific to the targeted cancer and does not bind to the same target on non-cancer cells, or that the receptor in the cell therapy does not recognize a similar peptide or protein derived in normal cells.

***Our Cell Therapies***

We have developed a range of cell therapies all of which utilize the interaction between a T-cell via its TCRs and a peptide or protein. Our cell therapies are made directly from a patient’s own T-cells (“autologous” cell therapies).

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For all of our autologous cell therapies patient T-cells are extracted and are then engineered to generate the end cell therapy whether this is through engineering of the TCR itself or through the addition of another agent which enhances the efficacy of the TCR or T-cell. The nature of the engineering impacts the type of cell therapy product generated. The engineered T-cells are then expanded and infused back into the patient. When these T-cells encounter a recognized peptide or protein within the patient's body, they multiply and initiate the destruction of the targeted cancer cells.

Adaptimmune has two receptor platforms, "TCRs" and "TRuCs", which target different classes of antigen. Engineered TCRs target peptides from intracellular proteins that are naturally processed into peptide fragments and presented on the cell surface by HLA, whereas TRuCs bind to protein targets that are expressed on the cell surface, similar to the way in which Chimeric Antigen Receptor or "CAR" T-cells act. Following identification of a suitable target protein that is expected to have a safe expression profile, we tailor our approach depending on the extracellular or intracellular location of the target.

For intracellular target proteins we identify potential immunogenic peptides that are processed and presented by specific HLA types and then identify TCRs that are capable of binding to that specific peptide/HLA complex. We engineer and optimize those identified receptors to enhance their ability to recognize and bind to the cancer targets, thereby enabling a highly targeted immunotherapy which complements a patient's immune system. The optimized TCR for the cell therapy then undergoes extensive preclinical safety testing prior to administration to patients who express the right protein target and HLA type. The majority of our products, current clinical candidates and most of our pre-clinical candidates target intracellular antigens presented by HLA-A2.

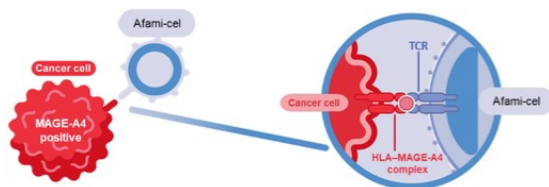
TRuCs use an antibody binding domain coupled to a CD3 subunit. The antibody portion binds to the target protein on the cancer cell and then the bound complex signals through a CD3/TCR complex using the natural signaling pathway of T cells. The physiological signaling method of TRuCs is distinct from CAR T-cell signaling where multiple signaling units are combined in a single protein. Natural TCRs are sensitive to much lower antigen density than CARs. Our ADP-520 preclinical program uses a TRuC directed to the CD70 antigen. There is no HLA restriction with this product meaning that all patients with tumors expressing CD70 could be eligible.

### **Our programs**

#### ***TECELRA***

In August 2024 we received accelerated approval from the FDA for TECELRA (famitresgene autoleucel or afami-cel) for adults with unresectable/metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A\*02 eligible, and whose tumor expresses MAGE-A4 as determined by FDA-approved diagnostics.

Afami-cel consists of autologous T-cells engineered to express an affinity enhanced TCR targeting a MAGE-A4 peptide presented on cancer cells by certain human leukocyte antigens (HLAs).



Afami-cel, afamitresgene autoleucel; HLA, human leukocyte antigen; MAGE-A4, melanoma-associated antigen A4; TCR, T-cell receptor.

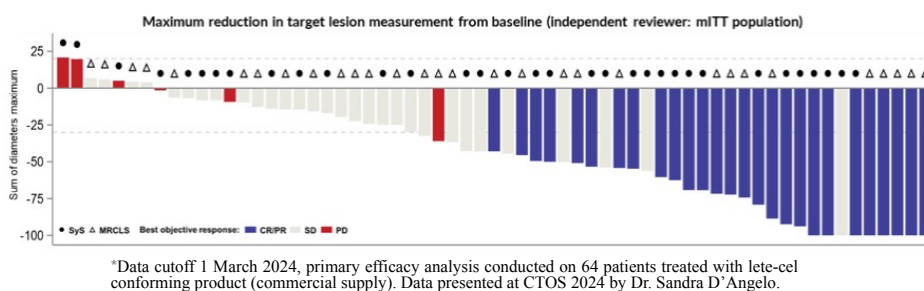
The approval of TECELRA was based on results from the SPEARHEAD-1 (Cohort 1) trial. In the primary analysis from the SPEARHEAD-1 trial, the pivotal trial for afami-cel, 52 patients were treated in cohort 1 of the trial. 44 synovial sarcoma patients and 8 myxoid liposarcoma patients. The overall response rate in the trial was 37% (19 out of

52 patients). Follow-up remains ongoing and as of August 30, 2023 median overall survival across synovial sarcoma and myxoid liposarcoma patients was 15 months. The median duration of response was 11.6 months in patients with synovial sarcoma and 4.2 months in patients with myxoid liposarcoma. Cytopenias were the most common Grade  $\geq 3$  adverse events. Cytokine release occurred in 71% of patients, with one grade 3 event. One patient had immune effector cell-associated neurotoxicity syndrome (Grade 1). Data from the analysis were reported in the Lancet in March 2024 (Lancet 2024;403: 1460-71).

There are more than 50 different types of soft tissue sarcomas which are categorized by tumors that appear in fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. Synovial sarcoma accounts for approximately 5 to 10% of all soft tissue sarcomas (there are approximately 13,400 new soft tissue cases in the U.S. each year). One third of patients with synovial sarcoma will be diagnosed under the age of 30. The five-year survival rate for people with metastatic disease is approximately 20% and most people undergoing standard of care treatment for advanced disease experience recurrence and go through multiple lines of therapy, often exhausting all options.

### ***Lete-cel*** (“lete-cel”)

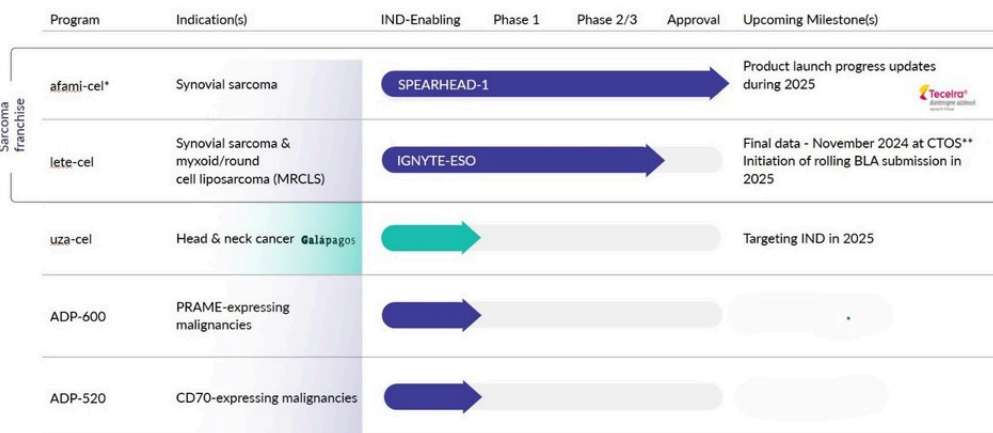
Lete-cel targets the NY-ESO antigen and has been in clinical trials (the IGRYTE-ESO trial) for people with synovial sarcoma and myxoid round cell liposarcoma (myxoid liposarcoma). Final data for the IGRYTE-ESO trial were reported at the Connective Tissue Oncology Society Annual Meeting (“CTOS”) in November 2024. In the Phase II analysis, 27/64 (42%) people with synovial sarcoma or myxoid liposarcoma had RECISTv1.1 responses by independent review, with 6 complete responses and 21 partial responses. The response rate was 14/34 (41%) for people with synovial sarcoma and 13/30 (43%) for people with myxoid liposarcoma. The median duration of response (DoR) was reported as 12.2 months. In synovial sarcoma, the median duration of response was reported as 18.3 months and in myxoid liposarcoma, the median duration of response was reported as 12.2 months. Safety findings were consistent with the known profile of lete-cel from previous data. All patients experienced treatment-emergent adverse events: cytopenias, cytokine release syndrome (CRS) and rash were the most common adverse events. Overall, toxicities were manageable, and consistent with an acceptable benefit to risk profile.



In January 2025, lete-cel was granted breakthrough therapy designation by the U.S. FDA for the treatment of patients with unresectable or metastatic myxoid liposarcoma who have received prior anthracycline-based chemotherapy, are positive for HLA-A\*02:01, HLA-A\*02:05, or HLA-A\*02:06, and whose tumor expresses the NY-ESO-1 antigen. We previously received breakthrough therapy designation for lete-cel in synovial sarcoma in 2016. This breakthrough designation is designed to expedite drug development and review processes. The criteria for this designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.



**Pipeline**



\*Afami-cel also being investigated in the pediatric basket trial SPEARHEAD-3.

\*\*Data cut-off 1 March 2024, primary efficacy analysis conducted on 64 patients treated with lete-cel protocol (commercial supply). Data presented at CTOS 2024 by Dr Sandra D'Angelo

**Clinical Programs**

We have a pediatric trial ongoing in the US in tumors expressing the MAGE-A4 antigen. Enrollment in our other ongoing clinical trials has ceased including the SURPASS-3 Phase 2 Trial in ovarian cancer.

We anticipate filing a clinical trial authorization for a Phase 1 trial in Head and Neck Cancer in collaboration with Galapagos during 2025. The trial will utilize ADP-5701, uza-cel manufactured using Galapagos' innovative decentralized cell therapy manufacturing platform. Uza-cel has shown encouraging results in head and neck cancer with partial responses in four out of five patients to date in a Phase 1 trial using Adaptimmune's manufacturing platform.

**Pre-Clinical Programs**

Our preclinical pipeline is focused on the development of T-cell therapies directed to PRAME (ADP-600) and CD70 (ADP-520). We have paused spend on these preclinical programs.

- PRAME is highly expressed across a broad range of solid tumors including ovarian, endometrial, lung and breast cancers. We are developing TCR T-cells directed to PRAME, with the initial candidate (ADP-600) currently in preclinical testing and next-generation candidates being developed over the longer term. We anticipated filing an IND for a Phase 1 trial with ADP-600 in 2025. ADP-600 has demonstrated high potency towards PRAME-positive tumor cells in pre-clinical testing.
- The CD70 program targets the CD70 antigen which is expressed across a range of hematological malignancies (acute myeloid leukemia and lymphoma) and solid tumors (renal cell carcinoma). We are using TRuC technology to develop a T-cell therapy (ADP-520) against CD70, with membrane bound IL-15 to enhance persistence. ADP-520 is currently in pre-clinical testing. The TRuC technology combines the targeting of CAR-T cells with T-cell TCR signaling.

## **Core Alliances and Collaborations**

### **Galapagos collaboration**

We entered in a clinical collaboration agreement with Galapagos in May 2024. Under the collaboration agreement we will conduct a clinical proof-of-concept trial to evaluate the safety and efficacy of uza-cel (ADP-5701, our next-generation MAGE-A4 targeting TCR T-cell therapy) produced on Galapagos' decentralized manufacturing platform in patients with head and neck cancer. Under the collaboration agreement, Adaptimmune is entitled to an initial payment of \$100 million, comprising \$70 million upfront and \$30 million of R&D funding, of which \$85 million has been received and \$15 million is due once the first patient is infused in the POC Trial. Galapagos has an option to exclusively license uza-cel for development and commercialization in head and neck cancer and potentially other solid tumor cancer indications. The option exercise fees under the agreement are up to \$100 million (dependent on the number of indications in relation to which the option is exercised) with additional development and sales milestone payments of up to \$465 million plus tiered royalties on net sales.

### **Genentech and GSK collaborations**

Prior collaborations with Genentech, relating to the research of "off-the-shelf" cell therapies, and GSK, relating to the transition of the NY-ESO and PRAME programs, have now either terminated or been concluded.

- In September 2024, we entered into a Mutual Release Agreement with Genentech which, among other things, resolved and released each party from any and all past, present and future disputes, claims, demands and causes of action, whether known or unknown, related to the Genentech Collaboration Agreement in any way. Under the terms of the Mutual Release Agreement, Genentech has paid \$12.5 million. On receipt of the payment the Genentech Collaboration Agreement was terminated.
- In April 2023, we entered into a Termination and Transfer Agreement with GSK regarding the return of the PRAME and NY-ESO cell therapy programs. As part of that agreement sponsorship of the IGNYTE and LTFU clinical trials relating to the NY-ESO cell therapy program transferred from GSK to us. In return for this, we received an upfront payment of £7.5 million with further milestones £22.5 million becoming paid through the remainder of 2023 and 2024. All payments have now been received under the agreement.

### **Intellectual Property**

We seek to protect the intellectual property and proprietary technology that we believe is important to our business, including seeking, maintaining, enforcing and defending patent rights for our cell therapies and processes, whether developed internally or licensed from third parties. Our success will depend on our ability to obtain and maintain patent and other protection including data/market exclusivity for our cell therapies, manufacturing and platform technology, preserve the confidentiality of our know-how and trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. See "Risk Factors—Risks Related to Our Intellectual Property."

Our policy is to seek to protect our proprietary position generally by filing an initial priority filing at the U.K. Intellectual Property Office ("UKIPO") and/or the U.S. Patent Trademark Office ("USPTO"). This is followed by the filing of a patent application under the Patent Co-operation Treaty ("PCT") claiming priority from the initial application(s) and then application for patent grant in, for example, the U.S. and Europe (including major European territories). In each case, we determine the strategy and territories required after discussion with our patent professionals to ensure that we obtain relevant coverage in territories that are commercially important to us and reflect the scope of cell therapies being developed. We will additionally rely on data exclusivity, market exclusivity and patent term extensions when available, including as relevant exclusivity through orphan or pediatric drug designation. We also rely on trade secrets and know-how relating to our underlying platform technologies, manufacturing processes and pre-clinical candidates.

### ***Product Patent Families***

***Afami-cel*** - We own multiple patent families covering the composition of matter of ADP-A2M4 and other related TCRs and T-cell therapies. The patent application claims are primarily directed to the engineered TCR therapeutic candidate and in particular the amino acid substitutions required for such engineered TCR therapeutic candidate. National/regional applications have been filed via the PCT in all commercially relevant territories and claims have been granted in Europe and the U.S. and other major jurisdictions. The patents within these families, if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will expire in 2037 (worldwide, excluding possible patent term extensions). National/regional patent applications have also been filed via the PCT in relation to the use of ADP-A2M4 TCR in the treatment of head and neck, lung and ovarian cancers.

***Lete-cel*** – We own a patent family covering the composition of matter of NY-ESO TCRs and T-cell therapies, with claims directed to engineered NY-ESO TCR therapeutics. Claims have been granted in Europe and the U.S. and other major jurisdictions, and the patents are expected to expire in 2025 (worldwide, excluding possible patent term extensions).

***PRAME TCR T-cell*** – We have filed a PCT application covering the composition of matter of the TCR T-cell therapy family directed to the PRAME target. The patent application claims are primarily directed to the engineered TCR candidate and in particular to the amino acid substitutions required for such TCR candidate. National and regional applications will be filed via the PCT in due course.

***CD70 TRuC T cell*** – We own a patent family covering the composition of matter of T cell therapies directed to CD70. National and regional applications have been filed in commercially relevant jurisdictions, and patents within these families, if issued, are expected to expire in 2041 (worldwide, excluding possible patent term extensions).

### ***Platform Technologies***

We own a number of platform technology patents and patent applications which are directed to certain aspects of the process that we use to engineer our TCRs and other cell therapies. Some of these are owned jointly with Immunocore Limited, with whom we have historically had a shared development history. We also own a patent family covering our TRuC-T cell platform, in which national/regional applications have been filed via the PCT in all commercially relevant territories. Patents with claims covering the TRuC-T cell platform have been granted in Europe, the US, and other major jurisdictions, and are expected to expire in 2036 (worldwide, excluding possible patent term extensions).

### ***Manufacturing Process Patents and Patent Applications***

We have trade secrets and patent applications relating to the manufacture of our cell therapies. For example, we have filed patent applications in commercially relevant territories, which claim priority from initial priority patent applications filed at the USPTO and UKIPO, which are directed to a particular modification to the lentiviral vector technology. We believe this modification enhances the safety profile of the lentiviral vector technology. This has been granted in the U.S. and other major jurisdictions. Further patent applications have been filed on the manufacturing and quality control of our products.

### ***Preclinical and Next-Generation Approaches***

We have filed patent families covering a range of next-generation technology approaches and/or combination approaches. For one of these patent families, we hold an exclusive, worldwide, royalty free, sublicensable license from Drs. Stefan Endres and Sebastian Kobold at the Klinikum der Universität München. We own the remaining patent families.

### ***Third-Party Intellectual Property Rights***

Whether licenses are required under any third-party patents depends on what steps we take going forward in relation to our manufacturing processes, development processes and development products including our allogeneic manufacturing and differentiation process. We may need to negotiate a license under any third-party patents or develop alternative strategies for dealing with any third party patents if licenses are not available on commercially acceptable terms or at all.

### **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies and intense competition. Competitors include large pharmaceutical companies with established development and commercialization programs, biotechnology companies with varying development and commercialization capabilities, and academic centers developing novel technologies and products.

We face competition in all of the following areas:

- (a) From other autologous cell therapies: There are a number of other cell therapies that have already received marketing approval or are currently in clinical trial development. For example, autologous CAR T-cells modalities on the market include Abecma™, Breyanzi™, CARVYTKI™, Tecartus™, Kymria™, and Yescarta™. In addition, other autologous cell therapies include TIL therapy (e.g. Iovance's AMTAGVI™).
- (b) From other TCR T-cell therapies: Third parties and academic institutions are developing cell therapies for single or multiple cancer and tumor microenvironment targets including personalized neoantigen targets. These cell therapies are at a variety of preclinical and clinical development stages. Examples include Immatics' IMA203 and IMA203CD8 assets that recognize a PRAME pHLA complex, which is currently being investigated across various solid tumor indications.
- (c) From other cell-based immunotherapy approaches: The immune system utilizes a complex range of different cell types and processes. Other immunotherapy approaches may target different parts of the immune system including different types of T-cells (for example, gamma delta T-cells), macrophage-based systems, NK-cell-based products, marrow-infiltrating lymphocytes (MILs) and dendritic-cell based systems.
- (d) From other allogeneic cell therapy approaches: Multiple third parties are currently developing allogeneic cell therapy approaches. These can be derived from healthy donors (for example Allo-501A from Allogene Therapeutics), umbilical cord blood, or induced pluripotent stem cells (for example, FT819 being developed by Fate Therapeutics). In Dec 2022, Atara Bio's donor-derived Eballo™ was granted approval from the European Commission for both adults and children with Epstein-Barr positive post-transplant lymphoproliferative disorder.
- (e) From other therapeutic product types. In any indication that we address, there may be multiple other product modalities that are already being marketed or in clinical trial development. For example, small molecule chemotherapy agents, biologics (e.g. peptides, antibodies, antibody-drug conjugates), vaccines, oncolytic viruses, other cell therapies (for example, gamma delta T-cells, macrophage-based systems, NK-cell-based products, marrow-infiltrating lymphocytes, and dendritic-cell therapies). Product approvals and new clinical trials can impact our ability to complete clinical development and obtain information about the safety and efficacy of our products.

Where we see competition in any indication and a competitor receives marketing approval before our cell therapy, we will need to demonstrate increased efficacy over the competing product.

## **Government Regulation and Product Approvals**

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, including the EU and U.K, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. Failure to comply with the various federal, state and local level laws and requirements can also result in severe penalties and restrictions to the business.

### ***FDA Approval Process***

In the U.S., therapeutic products, including drugs, biologics, and medical devices are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDCA"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products, including biological products. Biological products are subject to regulation under the FDC Act, and are approved for marketing under provisions of the Public Health Service Act ("PHSA") via a BLA. The application process and requirements for approval of BLAs are generally similar to those for new drug applications ("NDAs"), and biologics are associated with generally similar, if not greater, approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

In the U.S., the development of a new biological product and certain changes to an approved biological product typically involves:

- preclinical studies, including laboratory and animal tests,
- the submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical testing may commence, and
- adequate and well-controlled clinical trials to establish the safety and effectiveness of the biological product for each indication for which FDA approval is sought.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

### ***Preclinical Studies***

Preclinical studies include laboratory evaluation of product biochemistry, formulation and stability, as well as *in vitro* and animal studies to assess the potential for toxicity and to establish a rationale for therapeutic use for supporting subsequent clinical testing. In the United States, certain preclinical trials must comply with the FDA's Good Laboratory Practice requirements ("GLPs") and the U.S. Department of Agriculture's Animal Welfare Act, as well as other federal regulations and requirements.

### ***IND Submission***

In order to begin clinical testing of an investigational biologic product, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, are submitted to the FDA as part of an IND application. An IND application is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after

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receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on “clinical hold”. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

### *Clinical Studies*

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor’s control, in accordance with Good Clinical Practice (“GCP”) requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an Investigational Review Board (“IRB”) for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk profile of the biologic and to provide adequate information for the labeling of the product.

The FDA may order a clinical hold, resulting in the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An Investigational Review Board (“IRB”) may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCPs and the FDA is able to validate the data. The sponsor of a clinical trial or the sponsor’s designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as [clinicaltrials.gov](http://clinicaltrials.gov).

In December 2022, Congress passed the Food and Drug Omnibus Reform Act (“FDORA”), which includes provisions related to diversity in clinical trial enrollment. Once the new provisions go into effect, sponsors conducting a phase three study or another pivotal study must submit a diversity action plan to the FDA by the time they submit their study protocol. The FDA may waive the requirement to submit a diversity action plan if a waiver is necessary due to the prevalence or incidence of the disease or condition that is the subject of the trial or the patient population that may use the drug or device, or if implementing a diversity action plan would be impracticable, or against the public health interest during a public health emergency. The FDA may apply a waiver on its own initiative or at the request of a sponsor. If a sponsor requests a waiver, the FDA must grant or deny a waiver within 60 days of receiving such a request.

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### *BLA Review Process*

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA licensure or approval of the BLA is required before marketing of the product may begin in the U.S. The BLA must include the results of all preclinical, clinical, and other testing, compilation of data relating to the product's chemistry, manufacture, and controls, as well as proposed labeling for the product.

Under the PDFUA, the FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. Under PDUFA, the FDA has agreed to certain performance goals in the review of BLAs. Under Standard Review, applications for new biologic products are reviewed within 10 months of the date the FDA "filed" the BLA (approximately 60 days after receipt); under Priority Review, BLAs are reviewed within six months of the date the FDA "filed" the BLA. Priority Review can be granted to a BLA if the FDA determines that the proposed biological product has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The FDA does not always meet its PDUFA goal dates for Standard and Priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current Good Manufacturing Practices ("cGMP") requirements. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel biological products or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes physicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval.

After the FDA evaluates the BLA, it issues either an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the drug with specific prescribing information ("labeling") for specific indications. A CRL indicates that the review cycle of the application is complete and FDA has determined that the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may identify substantial additional non-clinical or clinical testing, or data, that must be developed in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

As a condition of BLA approval, the FDA may require a Risk Evaluation And Mitigation Strategy ("REMS") to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries.

### *Expedited Development Programs*

The FDA is required to facilitate the development, and expedite the review, of certain biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment, which demonstrate the potential to address unmet medical needs for the condition, and/or would provide an improvement over existing therapies. These expedited programs include Fast Track designation, Breakthrough Therapy designation, Accelerated Approval, and Priority Review:

- Pursuant to Section 506(b) of the FDCA, Fast Track designation is available for drug and biological products that are intended to treat a serious or life-threatening condition and for which preclinical or clinical data

demonstrate the potential to address an unmet medical need. Fast Track designation applies to both the product and the specific indication for which it is being studied. For biologics, the sponsor can request the FDA to designate the product for Fast Track status any time before receiving a BLA approval, but ideally no later than the pre-BLA meeting. Fast Track designation provides for additional interactions with FDA to expedite development and review of the BLA, and may also allow for rolling submission and review of the BLA.

- Pursuant to Section 506(a) of the FDCA, Breakthrough Therapy designation is available if the product is intended, alone or in combination with one or more other drug products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Requests for Breakthrough Therapy designation should ideally be made prior to the End-of-Phase 2 Meeting.
- Accelerated Approval is available for drug or biological products that treat a serious or life-threatening condition and generally provide a meaningful advantage over available therapies. In addition, the product must demonstrate 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 (“IMM”), which is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a biologic receiving Accelerated Approval perform adequate and well-controlled confirmatory clinical trials in the post-marketing phase. If the FDA concludes that a biologic shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions as it deems necessary to assure safe use of the product. In December 2022, the passage of FDORA made several changes to the FDA’s Accelerated Approval program. Among other things, FDORA provides the FDA greater authority to ensure that sponsors begin confirmatory trials promptly, including prior to BLA approval. FDORA also provides the FDA with additional authority to withdraw approval of a product for which confirmatory studies are not completed or are inadequate to demonstrate a satisfactory benefit/risk profile.
- Under PDUFA, a BLA that receives Priority Review will have a 6-month goal date for first cycle review, rather than the 10-month goal date under Standard Review. To qualify for Priority Review, the FDA must determine that the biologic product has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The decision to grant Priority Review is made by the FDA within 60 days of receipt of the BLA.

Fast Track designation, Breakthrough Therapy designation, Priority Review, and Accelerated Approval generally do not change the standards for approval, but may expedite the development or approval process. Fast Track and Breakthrough Therapy designations may be rescinded later in product development if the product no longer meets the designation-specific qualifying criteria.

#### *Regenerative Medicine Advanced Therapy designation*

Under Section 506(g) of the FDCA, added as part of the 21st Century Cures Act, Congress created the RMAT designation to facilitate an efficient development program for, and expedite review of, a product candidate that meets the following criteria:

- it qualifies as an 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;
- it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and
- preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition.

A sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for Priority Review or Accelerated Approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or



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reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation include all the benefits of Fast Track and Breakthrough Therapy designation, including early interactions with FDA to discuss any potential surrogate or intermediate endpoints that could be used to support Accelerated Approval. In addition, a regenerative medicine therapy with RMAT designation that is granted Accelerated Approval and is subject to post-approval requirements may, as appropriate, fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like FDA's other expedited development programs, RMAT designation does not change the standards for approval but may help expedite the development or approval process. The RMAT designation may be rescinded later in product development if the product no longer meets the designation-specific qualifying criteria.

### *Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biological products intended to treat a rare disease or condition. A rare disease or condition is one that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there must be no reasonable expectation that the cost of developing and making a product available in the U.S. for such disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the biological product and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation confers several benefits, including certain tax credits for clinical research, a waiver of the BLA application fee, and exemption from certain pediatric study requirements, among others. The key benefit of orphan drug designation is orphan drug exclusivity, which is a seven-year exclusive marketing period in the U.S. for that product for that indication. Generally, the first BLA applicant with FDA orphan drug designation for a particular biological product to treat a particular disease that obtains FDA approval is entitled to orphan drug exclusivity. During the orphan drug exclusivity period, the FDA may not approve any other applications to market the same biological product for the same rare disease or condition, with limited exceptions. One exception is if the later application can demonstrate clinical superiority to the biological product with orphan drug exclusivity. Clinical superiority may be shown by greater efficacy, greater safety, or a major contribution to patient care.

Orphan drug exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same biological product for a different disease or condition.

### *Pediatric Data and Study Requirements*

Under the Pediatric Research Equity Act ("PREA"), NDAs or BLAs (as well as efficacy supplements) must contain data to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug or biological product is approved as safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant full or partial waivers, or deferrals, for submission of these assessments. Sponsors must also submit pediatric study plans ("PSPs") within sixty days of an end-of-phase 2 meeting, or as may be agreed between the sponsor and FDA. Those 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. The applicant, the FDA, and the FDA's internal pediatric review committee must then review the information submitted, consult with each other, and agree upon a final PSP. The FDA or the applicant may request an amendment to the plan at any time. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Under the Best Pharmaceuticals for Children Act ("BPCA"), a sponsor may qualify for "pediatric exclusivity" if it conducts pediatric studies in response to a Written Request issued by FDA. Pediatric exclusivity extends by 6 months the period of other regulatory exclusivities, such as orphan drug exclusivity, so long as those exclusivity periods will not expire within 9 months of the award of pediatric exclusivity. For drug products, pediatric exclusivity will also

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extend the preclusive effect of patents on the FDA's authority to approve certain competitor applications. Pediatric exclusivity does not extend patents for biological products approved under BLAs. To qualify for pediatric exclusivity, a sponsor must conduct studies that fairly respond to a Written Request, which outlines in detail the nature and type of studies that must be conducted. The studies need not show the product to be effective in the pediatric population; so long as the clinical studies are determined to fairly respond to the Written Request, pediatric exclusivity will be awarded. The FDA may issue a Written Request on its own initiative or at the sponsor's request. A Written Request can include multiple studies in both approved and "off-label" indications.

### *Additional Controls for Biologics*

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

### *Biosimilars*

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be "highly similar" to or "interchangeable" with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product must contain evidence to show that the biosimilar product is "highly similar" to an approved reference biological product, notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Data to show biosimilarity can include: (1) analytical studies; (2) animal studies; and (3) a clinical study or studies. The FDA has the discretion not to require each of these categories of data. A biosimilar can be approved by the FDA for some or all of the same conditions of use, strengths, dosage forms, and routes of administration as the FDA-approved reference product. The FDA will determine that a biosimilar product is interchangeable with its reference biological product, if the biosimilar product 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 biosimilar and the reference biologic 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 biologic. Whether products deemed "interchangeable" by the FDA will, in fact, be substituted by pharmacies is governed by state pharmacy law.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the product.

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The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biosimilar products for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar has been approved if a patent lawsuit is ongoing within the 42-month period.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to 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 impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

### *Post-Approval Requirements*

Approved drug and biological products are subject to ongoing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors 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, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market or product recalls;
- fines, warnings or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A sponsor may only make claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of “off-label” uses. Failure to comply with these requirements can result in, among other things, adverse publicity, untitled and warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those

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tested by us and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of "off-label" use of their products.

### *FDA Regulation of Companion Diagnostics*

If safe and effective use of a therapeutic product depends on an *in vitro* diagnostic, the FDA generally will require approval or clearance of the diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. The FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain marketing approval through the pre-market approval ("PMA") process for that diagnostic simultaneously with approval of the therapeutic. The review of these *in vitro* companion diagnostics in conjunction with the review of a cancer therapeutic involves coordination of review by the FDA's Center for Biologics Evaluation and Research ("CBER") and by the FDA's Center for Devices and Radiological Health ("CDRH").

The PMA process involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought.

Successful PMA approval is uncertain, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA finds the PMA application is approvable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

### *Anti-Kickback, False Claims Laws*

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes, and other statutes pertaining to health care fraud and abuse. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the Healthcare Reform Act amended the federal false claims law such that a violation of the federal healthcare program anti-kickback statute can serve as a basis for liability under the federal false claims law.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror/payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the healthcare fraud statute, which prohibits knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses,

representations, or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

#### *Pricing and Reimbursement*

Sales in the United States of approved biological products are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid.

Participation in the Medicaid Drug Rebate program, state Medicaid supplemental rebate program(s), and other governmental pricing programs will include certain price reporting obligations, as well as obligations to report the average sales price for certain drugs to the Medicare program. Under the Medicaid Drug Rebate program, sponsors are required to pay a rebate to each state Medicaid program for our covered outpatient drugs and biologics that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available for our drugs under Medicaid and Part B of the Medicare program.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Medicaid rebates are based on pricing data reported by sponsors on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers the Medicaid and Medicare programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug or biologic which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. The amount of the rebate is adjusted upward if average manufacturer price increases more than inflation (measured by reference to the Consumer Price Index - Urban). Until December 31, 2023, the rebate was capped at 100 percent of the average manufacturer price, but effective January 1, 2024, this cap on the rebate has been removed, and the rebate liability of manufacturers could increase accordingly.

If a sponsor becomes aware that Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, the sponsor is obligated to resubmit the corrected data for up to three years after those data originally were due, which revisions could affect rebate liability for prior quarters. If a sponsor fails to pay the required rebate amount or report pricing data on a timely basis, the sponsor may be subject to civil monetary penalties and/or termination of its Medicaid Drug Rebate program agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for covered outpatient drugs. The federal Patient Protection and Affordable Care Act ("PPACA") made significant changes to the Medicaid Drug Rebate program, and CMS subsequently issued a final regulation to implement the changes to the Medicaid Drug Rebate program under PPACA. CMS has since modified its Medicaid Drug Rebate program regulations to, among other things, permit reporting multiple best price figures with regard to value-based purchasing arrangements and provide definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drug and biological products considered to be line extensions. In addition to Medicaid we are required to provide rebates to Veteran Affairs/Department of Defense and 340B facilities.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part A and Part B will apply to our cell therapies. Medicare Part A will apply for inpatient care for Medicare beneficiaries. Medicare Part B generally covers drugs and biologics that must be administered by physicians or other health care practitioners; are provided in connection with certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs and biologics under a payment methodology based on the average sales price of the drugs. Manufacturers are required to report average sales price information to CMS on a quarterly basis. The manufacturer-submitted information may be used by CMS to calculate Medicare payment rates. Manufacturers must pay refunds to Medicare for single-source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties. Further, the Inflation

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Reduction Act (“IRA”) has established a Medicare Part B inflation rebate scheme under which, generally speaking, manufacturers owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty.

The IRA also created a drug price negotiation program requiring the government to set prices for select high-expenditure drugs covered under Medicare Parts B and D. Starting in 2023 and 2026, the government is authorized to select Part D and Part B drugs, respectively, for inclusion in the drug price negotiation program, with established prices to go into effect for selected Part D drugs in 2026 and for selected Part B drugs in 2028, in each case absent certain disqualifying events. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and a civil monetary penalty. The IRA’s drug price negotiation program is the subject of ongoing litigation, and its implementation remains unclear.

Private payor healthcare and insurance providers, health maintenance organizations, and pharmacy benefit managers in the United States are adopting more aggressive utilization management techniques and are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment/coinsurance. These payors may not cover or adequately reimburse for use of our products or may do so at levels that disadvantage them relative to competitive products.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

### *Sunshine Act and Transparency Laws*

The US Physician Payments Sunshine Act (“Sunshine Act”) requires applicable manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The Sunshine Act thus requires tracking of such payments and transfers of value, reporting to the federal government, and public disclosure of certain data.

A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to healthcare providers in the states. Government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports.

### ***Other Federal and State Regulatory Requirements***

Various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, the environment and the purchase, storage, movement, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research are applicable to our activities. They include, among others, the U.S. Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation.

### ***European Union, U.K. and Rest of the World Regulation***

In addition to regulations in the U.S., we are subject to a variety of regulations in other jurisdictions both due to the location of our facilities and the fact that we are engaging in clinical programs outside of the U.S. and will need to obtain worldwide regulatory approval for our TCR therapeutic candidates. In particular we have clinical trials ongoing in the United Kingdom and in certain countries in the European Union (“EU”) and are subject to regulations relating to performance of those clinical trials and manufacture and supply of our cell therapies in those countries. Prior to supplying any cell therapy in any country or starting any clinical trials in any country outside of the U.S. we must obtain the requisite approvals from regulatory authorities in such countries. The existence of a U.S. regulatory approval does not guarantee that regulatory approvals will be obtained in other countries in which we wish to conduct clinical trials or market our cell therapies. In the EU, for example, a clinical trial application must be submitted to each country’s national health authority and an independent ethics committee, much like the FDA and IRB, respectively prior to any clinical trial being conducted in the relevant country. A marketing authorization application is then submitted to the EMA for approval by the European Commission. Finally, prior to any commercial supply, a pricing and reimbursement application is submitted to each relevant country’s national or local health authorities.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with Good Clinical Practice (“GCP”) and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. However, the interpretation of these requirements may well differ from country to country.

#### *Review and Approval of Drug Products Outside of the U.S.*

In order to market any product outside of the U.S., a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

#### *Procedures Governing Approval of Products in the EU and U.K.*

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a EU member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. A clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents. Similar approval requirements apply in the U.K. and a clinical trial application must be made to the U.K. regulatory authority (“MHRA”) prior to starting any clinical trial.

To obtain marketing approval of a product under EU regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

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Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the scientific assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. For advanced therapy medicinal products (“ATMPs”), the scientific evaluation of MAA is primarily performed by the Committee for Advanced Therapies (“CAT”). The CAT prepares a draft opinion of each ATMP subject to a MAA which is sent for final approval to the CHMP.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days. Then, the European Commission grants or refuses the marketing authorization, following a procedure that involves representatives of the member states. Although the CHMP's opinion is not binding, the Commission's decision to grant or refuse the market authorization is frequently in accordance with the CHMP's assessment except in very rare cases. For marketing approval in the U.K, an application for marketing approval will be made for the MHRA and follows a similar process to that used in the EU.

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state or in the U.K. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

As a result of Brexit, as of January 1, 2021, marketing authorizations granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland, but not in Great Britain (England, Scotland and Wales). However, prior EU authorizations have all been automatically converted into U.K. marketing authorizations effective in Great Britain. U.K. rules require marketing authorization holders to be established in the U.K. or in the EU/European Economic Area. EU rules require marketing authorization holders to be established in the EU/European Economic Area and, in addition, that certain activities be performed in the EU, related for example to pharmacovigilance, batch release and quality control. Marketing authorization holders may need to take steps to comply with these requirements aiming at holding both a EU and a U.K. marketing authorization.

With regard to the sunset clause, from the perspective of the U.K, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain marketing authorization. From the perspective of the EU, in case the drug has been marketed in the U.K, the placing on the U.K. market before the end of the Brexit transition period will be taken into account. If, after the end of the Brexit transition period, the drug is not placed on any other market of the remaining member states of the EU, the three year period for the sunset clause will start running from the last date the drug was placed on the U.K. market before the end of the Brexit transition period.

Outside the U.S., interactions between biopharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products, which is prohibited in the EU, is governed by the national anti-bribery laws of the EU member states. Violation of these laws could result in substantial fines and imprisonment. Certain EU member states, or industry codes of conduct, require that payments made to physicians be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member



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states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

***Privacy and Data Protection laws***

There are numerous state, federal and foreign laws governing the collection, processing, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. Further, certain foreign laws govern the privacy and security of personal data, including health-related data. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. These laws are constantly evolving and often require extensive resources to maintain and manage.

**Legal Proceedings and Related Matters**

From time to time, we may be party to litigation that arises in the ordinary course of our business. On December 2, 2024, the University of Texas M.D. Anderson Cancer Center (“MD Anderson”) served litigation in the District Court of Harris County against Adaptimmune LLC (“Adaptimmune”). The litigation relates to a Strategic Alliance Agreement between MD Anderson and Adaptimmune dated September 23, 2016. The case has not yet proceeded to discovery stage and we do not believe there is any merit to the claims being brought by MD Anderson.

**Employees and Human Capital Management**

As of December 31, 2024, we had 506 employees. Of these employees, 384 were in research and development (including in manufacturing and operations, and quality control and quality assurance), 17 were in commercial and 105 were in management and administrative functions (including business development, finance, intellectual property, information technology and general administration). We have never had a work stoppage and none of our employees are covered by collective bargaining agreements or require representation by a labor union.

In November 2024, we announced that we were reducing our headcount by approximately 33% with the actual reduction in headcount being approximately 29%. As of the end of February 2025, the majority of the headcount restructuring has been completed.

We value our employees and as a company work hard to employ those individuals that will work with us to achieve the objectives of the Company and share our values. We engage with our employees in multiple ways including through companywide business meetings, social events and smaller team events. We employ individuals based on their experience and ability to perform the applicable job and encourage diversity in our workforce whenever possible. We have an equal opportunities policy which promotes the right of every employee to be treated with dignity and respect and not to be harassed or bullied on any grounds.

We have a performance-based reward scheme, bonus scheme and share option plan which all employees are entitled to participate in. These schemes and other employee incentive programs are designed to retain employees. For 2024, the total global attrition rate was approximately 11%.

**Other Information**

The Company’s primary website is [www.adaptimmune.com](http://www.adaptimmune.com). Information in the investor section and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. The Company makes available, free of charge, at its corporate website, its Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as soon as reasonably practicable after they are electronically filed with the Securities and Exchange

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Commission (“SEC”). The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).

**Item 1A. Risk Factors.**

*Our business has significant risks. You should carefully consider the following risk factors as well as all other information contained in this Annual Report, including our consolidated financial statements and the related notes, before making an investment decision regarding our securities. The risks and uncertainties described below are those material risk factors currently known and specific to us that we believe are relevant to our business, results of operations and financial condition. Additional risks and uncertainties not currently known to us or that we now deem immaterial may also impair our business, results of operations and financial condition.*

**Risk Factors Summary**

The following is a summary of the principal risks that could adversely affect our business.

**Risks Related to Our Financial Condition and Capital Requirements**

- We have incurred net losses every year since inception and expect to continue to incur net losses in the future. If we are unable to obtain additional financing or funding we may be unable to complete the development and commercialization of our cell therapies.
- We may never generate sufficient revenue from sales of our cell therapies and become profitable and our generation of additional revenue depends on our ability to timely progress our cell therapies through development and successful commercialization.
- Although our financial statements have been prepared on a going concern basis, there is substantial doubt about our ability to continue as a going concern.

**Risks Related to the Commercialization and Marketing of Our Cell Therapies**

- We are dependent on successful commercialization of TECELRA which is dependent on a number of factors including our ability to operationalize ATCs, the uptake by physicians and number of patients eligible for treatment and availability of reimbursements for TECELRA.
- We have never commercialized a product as a company and our ability to commercialize is dependent on our ability to increase manufacturing capacity, set up processes and recruit employees required for such commercialization.
- We may not be able to obtain marketing approvals of our cell therapies as broadly as planned or on the timescales we plan including for lete-cel.
- We may not be able to adequately price our cell therapies due to regulatory changes affecting pricing, coverage, and reimbursements or to other impacts such as inflation, increasing underlying raw material costs, availability of materials, or increasing third party supply chain costs.
- We may not be able to prepare and develop a full network of clinical sites for administration of TECELRA as planned which will reduce the number of patients we are able to treat.
- We will have a narrow network of sites which may not be assessable to all patients for TECELRA.
- We may not be able to realize the projected market demand for our cell therapy products.

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- We may not be able to set up and maintain a distribution and logistics network capable of supply and storage of our cell therapy products to enable timely delivery to clinical sites and patients.
- Sales of our cell therapies are dependent on the availability and extent of coverage and reimbursement from third-party payors, including private payors and government programs such as Medicare and Medicaid.
- Product reimbursement and coverage policies and practices could change due to various factors such as drug price control measures that have been or may be enacted or introduced in the U.S. by various federal and state authorities.
- The commercial success of our cell therapies is subject to significant competition from product candidates that may be superior to, or more established, or cost effective than, our cell therapies.
- If the testing or use of our cell therapies harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

**Risks Related to the Development of Our Cell Therapies**

- Our ability to fund our business and continue to develop our cell therapies is dependent on the data obtained from our ongoing clinical trials.
- Our clinical trials and clinical data are at an early stage and future data may not support continued development of our cell therapies.
- Clinical trials are time consuming and expensive, and we may not be able to recruit patients as planned. External factors such as pandemics or geopolitical instability, for example the Russian/Ukrainian conflict may also impact ability to perform clinical trials as planned.
- Our cell therapies are novel, and there is an increased risk that we may see unacceptable toxicities.

**Risks Related to the Manufacture and Supply of Our Cell Therapies**

- Manufacture of cell therapies is complex, and we may encounter difficulties manufacturing and supplying our cell therapies to patients, whether for clinical trials or for commercial purposes.
- We have our own manufacturing facility which is the sole source of supply for TECELRA and afami-cel. Our ability to manufacture cell therapies is dependent on our ability to operate the facility in compliance with Good Manufacturing Practice (“GMP”), maintain regulatory approvals for the facility, recruit and train employees required for manufacture, manufacture cell therapies reliably and reproducibly, and ensure manufacturing and supply capacity to meet the required demand.
- We are reliant on third parties for the manufacture of the vector and for the manufacture of our lete-cel cell therapy. We will be reliant on Galapagos NV for manufacture of uza-cel product for the clinical proof-of concept trial under the collaboration.

**Risks Related to Government Regulation**

- We are subject to significant regulatory, compliance and legal requirements and will continue to be subject to these requirements.
- We have obtained accelerated approval for TECELRA and additional requirements apply before we can obtain full approval. We do not know if the FDA will accept our application for full approval or whether additional obligations or requirements will be imposed.

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- Any commercialization of our cell therapies will also require approval for companion diagnostics, which may result in additional regulatory, commercialization and other risks. We are reliant on a third party for development of any companion diagnostic including the companion diagnostics for our TECELRA and lete-cel products.
- We have post-marketing obligations imposed by the FDA as a result, in part, of the approval of TECELRA under the FDA's Accelerated Approval pathway. We are required to conduct and submit the required responses including results from further cohort of the SPEARHEAD-1 trial. Such obligations increase the costs and resources associated with launch of TECELRA and the costs of commercializing afami-cel.
- We intend to submit a rolling BLA for lete-cel starting in 2025. We do not know whether the FDA will accept the filing of that BLA, whether they will approve lete-cel for marketing or whether prior to such approval they will require additional obligations, data (including additional clinical investigations) or other requirements to be met before approving the BLA.

### **Risks Related to Our Reliance Upon Third Parties**

- We are reliant on third parties for provision of services including manufacturing services, commercialization services and clinical research services including for the commercialization of TECELRA, manufacture of vector and lete-cel, provision of components and materials required for manufacturing, research and development and for the performance of our collaborations.

### **Risks Related to Our Intellectual Property**

- We may be forced to litigate to defend our intellectual property rights and we may be subject to patent infringement proceedings brought against us by third parties.
- Our ability to be competitive depends, in part, on our ability to protect our proprietary technology including through patents and through maintaining confidentiality in our trade secrets.

### **Risks related to litigation**

- We have been served with litigation by the University of Texas M.D. Anderson Cancer Center ("MD Anderson") in the District Court of Harris County against Adaptimmune LLC ("Adaptimmune"). The litigation is at an early stage and the costs of such action and outcome of such proceedings cannot be predicted.

### **General Business Risks**

- We may face litigation from third parties
- Our inability to continue to attract and retain qualified personnel may hinder our business.
- We expect to face intense competition from third parties and this competition may come from companies with significantly greater resources and experience than we have.
- Information technology systems may fail or suffer cybersecurity incidents including related to data protection and privacy laws and adversely affect our business and operations.
- We may not be able to maintain compliance with the continued listing requirements of Nasdaq.
- The market price of our ADSs is subject to volatility.

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- We are heavily reliant on third parties for the operation of our business including the manufacture of our cell therapies and our future supply and commercialization of afami-cel
- We have a sole source of supply for many of our cell therapy products and for some of the critical materials needed to manufacture those products.

For a more complete discussion of the risks we face as a business, please see the discussion below.

**Risks Related to Our Financial Condition and Capital Requirements**

*We have incurred net losses every year since our inception and expect to continue to incur net losses in the future.*

We have generated losses since our inception in 2008, during which time we have devoted substantially all of our resources to research and development efforts relating to our cell therapies, including engaging in activities to manufacture and supply our cell therapies for clinical trials, conducting clinical trials of our cell therapies, providing general and administrative support for these operations, enhancing capabilities to support commercialization for ADP-A2M4 and protecting our intellectual property. For the years ended December 31, 2024, 2023 and 2022, we incurred net losses of \$70.8 million, \$113.9 million and \$165.5 million, respectively. As of December 31, 2024, we had accumulated losses of \$1,094.0 million. We have only one product, TECELRA, approved for sale and have generated limited revenue from product supplies. Even though we have obtained marketing approval for our first cell therapies, TECELRA, it will take a period of time before any significant revenue is realized and the amount of revenue is heavily dependent on the success of our commercialization and the costs of supplies including any post-marketing requirements we are subject to.

*We are currently operating in a period of heightened economic, energy supply and material supply uncertainty as a result of the Russian/Ukrainian conflict and the Israel-Hamas conflict.*

The short and long-term implications of the conflict in Ukraine and the Israel-Hamas conflict are difficult to predict at this time. We continue to monitor any adverse impacts on the global economy, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, the conflict in Ukraine and Israel has resulted in increased inflation, escalating energy prices and constrained availability, and thus increasing costs of the raw materials we require in our business. In the event of prolonged conflict other risks to the business may also increase including adverse effects on macroeconomic conditions, including inflation; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

*Unstable market and economic conditions may have a serious adverse impact on our business and financial condition.*

Economic uncertainty in various global markets or the global economy may adversely affect our business. Any severe or prolonged economic downturn could result in a variety of risks to our business, including the inability to raise additional capital when needed or on acceptable terms. Uncertainty or a prolonged downturn may impact third-party suppliers and service providers, resulting in their inability to meet their commitments to us. The global credit and financial markets have experienced significant volatility and disruptions in recent years, driven by factors such as geopolitical tensions, including the Russia-Ukraine and Israel-Hamas conflicts, rising inflation, interest rate fluctuations, and most recently changes in trade policies and tariffs. In addition, political instability, including ongoing debates over U.S. fiscal policies, government shutdowns, and budgetary concerns, could further exacerbate uncertainty in global economic conditions. This volatility and political instability has resulted in diminished liquidity and credit availability, declines in consumer confidence, reduced economic growth, and in some economies and regions higher unemployment. The full impact of these factors is difficult to predict. If these conditions persist or further deteriorate it could exacerbate global economic uncertainty, lead to recessions in key markets, and disrupt international supply chains. These factors could make it materially more difficult for us to obtain financing in the capital markets or otherwise and could have a material adverse effect on our business, financial condition and results of operations.

***If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our cell therapies.***

We expect to continue incurring significant losses as we continue with our research and development programs and to incur general and administrative costs associated with our operations. The extent of funding required to develop our cell therapies is difficult to estimate given the novel nature of our cell therapies and their un-proven path to successful commercialization and we may not have anticipated all the costs required to meet our planned objectives. As of December 31, 2024, the Company had cash and cash equivalents of \$91.1 million, marketable securities of \$60.5 million, and stockholders' equity of \$11.8 million. We expect to use these funds to advance and accelerate the commercialization of TECELRA, clinical development of our cell therapies, to further develop and enhance our manufacturing capabilities and secure a commercially viable manufacturing platform for all of our cell therapies, to support development of lete-cel, to fund working capital, and for other general corporate purposes. The Company has identified conditions and events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. We announced a reduction in costs and head count at the end of 2024. We announced a pause in spend on the PRAME and CD-70 programs in March 2025 and are exploring strategic options for the Company and our programs. If we do not raise further funding we will not be able to fund our business as currently planned.

Our costs and expenses may increase significantly or our cashflow may be impacted significantly in the event of any of the following, any of which could have a material impact on our business and our ability to continue as a going concern:

- any additional requirement to outsource manufacture of our cell therapies to third parties, or acquire additional raw materials to support manufacture in the event of any inability to manufacture at our own facilities;
- any requirement to conduct additional or further clinical trials or to treat additional patients to satisfy the regulatory authorities that a cell therapy is safe or that it is efficacious and can be approved for marketing or to proceed to the next stage of development;
- any post-marketing requirement or additional regulatory requirement imposed in relation to the commercialization or approval of TECELRA or lete-cel;
- any requirement to vary, change or amend our current manufacturing processes;
- any requirement to materially vary any ongoing clinical trial protocol;
- third party litigation, including patent litigation, being brought against the Company and including the litigation brought by MD Anderson;
- a requirement to pay any third party upfront, milestone, royalty or other payments in order to continue to develop or commercialize any of our cell therapies, including our allogeneic cell therapies;
- a requirement to create additional infrastructure to support our ongoing operations, including future commercialization efforts;
- any inability to recruit patients to our clinical trials on a timely basis necessitating the need to open additional clinical sites or otherwise enable increased recruitment or to extend the duration of such trials;
- faster than expected recruitment of patients in our clinical trials or provision of commercial orders for TECELRA necessitating recruitment of additional resources to ensure cell therapies can be manufactured and provided to patients;

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- any unplanned capital expenditure including any requirement to increase or enhance manufacturing capability or invest in additional manufacturing facilities;
- changes in the timing on when we receive payments from our third party collaborators, in particular Galapagos;
- business activities and negotiations including agreements with third parties for collaborations, combinations, mergers or acquisitions which do not execute or finalize on suitable terms or do not complete as expected;
- any requirement to repay further loan amounts under the Loan Agreement through breach of covenants and obligations under the agreement or otherwise; or
- inability of third parties to provide critical supplies on a timely basis necessitating alternative or additional third party supplies to be put in place.

We may be unable to obtain additional funding on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will have to significantly delay, scale back or discontinue the development or commercialization of our cell therapies or other research and development initiatives. Inability to raise additional funding may result in a requirement to repay the remaining loan amounts under our Loan Agreement. Our license and supply agreements may also be terminated if we are unable to meet the payment obligations under these agreements. We could be required to seek collaborators for our cell therapies at an earlier stage than otherwise would be desirable or on terms that are less favorable to us than might otherwise be available or relinquish or license on unfavorable terms our rights to our cell therapies in markets where we otherwise would seek to pursue development or commercialization ourselves.

***Although our financial statements have been prepared on a going concern basis there is substantial doubt about our ability to continue as a going concern.***

As of December 31, 2024, the Company had cash and cash equivalents of \$91.1 million, marketable securities of \$60.5 million, and stockholders' equity of \$11.8 million. During the year ended December 31, 2024, the Company incurred a net loss of \$70.8 million, used cash of \$73.2 million from its operating activities, and generated revenues of \$178.0 million. The Company has incurred net losses in most periods since inception and it expects to incur operating losses in future periods. Having evaluated certain conditions and events, the Company has concluded that substantial doubt exists as to whether we can continue as an ongoing business within one year after the date the financial statements are issued.

We executed a restructuring of the company to reduce headcount and expenses in early 2025. We have paused spend on the PRAME and CD-70 preclinical programs. Despite this restructuring we must obtain additional capital to continue funding planned operations. We may be unable to obtain sufficient additional capital to continue funding our operations or, if we do, it may be insufficient and/or on terms that are unfavorable to our existing shareholders. Any future fundraising, if possible, is likely to be highly dilutive to our existing shareholders and may also divert our management from its day-to-day activities.

If the Company fails to obtain additional funding, it may be required to:

- further reduce or stop activities and operations of the business in order to reduce or eliminate ongoing expenditure. Any such reduction could significantly delay the timelines under which we can bring new products to the market (including lete-cel) or our ability to commercialize TECELRA;
- further reduce headcount and expenditure which will in turn reduce the activities and operations of the business;
- repay all or part of the remaining loan advances received under the Loan Agreement in accordance with the terms of the Loan Agreement (including any applicable repayment charges or costs);

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- seek further third party alliances for existing assets, including TECELRA, on terms that are less favorable than might otherwise be available;
- seek an acquirer for all or part of the business on terms that are less favorable than might otherwise be available; and
- relinquish or license on unfavorable terms or rights to technologies, intellectual property or product candidates we would otherwise seek to develop or commercialize ourselves.

Inability to obtain additional funding may also impact on existing business relationships resulting in termination or variation of those relationship.

***Our current cash projections include reliance on the ability to obtain certain tax credits and the operation of certain tax regimes within the U.K. Should these cease to be available or be reduced, this could impact our ongoing requirement for investment and the timeframes within which additional investment is required.***

As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime for small and medium sized companies, whereby our principal research subsidiary company, Adaptimmune Limited, is able to surrender the trading losses that arise from its research and development activities for a payable tax credit of up to approximately 33.4% of eligible research and development expenditures, decreasing to 18.6% after April 1, 2023. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects. Subcontracted research expenditures are eligible for a cash rebate of up to approximately 21.7%, decreasing to 12.1% after April 1, 2023. The majority of our pipeline research, clinical trials management and manufacturing development activities, all of which are being carried out by Adaptimmune Limited, are eligible for inclusion within these tax credit cash rebate claims.

The U.K. government has introduced some changes to the U.K. research and development credit rules. These changes may give rise to a reduction in our U.K. research and development credit claims in the future. These came into effect on February 22, 2024. These changes include combining the current SME R&D Tax Credit Scheme and RDEC Schemes with a single 20% gross rate applying to all claims with an exception for R&D Intensive SMEs. For entities which qualify as R&D Intensive SMEs, a higher effective cash tax benefit of 27% will be available. The legislation also includes changes to other rules and types of qualifying expenditure, such as the treatment of subcontracted and overseas costs. These changes may give rise to an increase in our U.K. research and development credit claims in the future if the Company qualifies as an R&D Intensive SME.

We may also benefit in the future from the U.K.'s "patent box" regime, which would allow certain profits attributable to revenues from patented products to be taxed at a rate of 10%. As we have many different patents covering our products, future upfront fees, milestone fees, product revenues, and royalties could be taxed at this favorably low tax rate. When taken in combination with the enhanced relief available on our research and development expenditures, we expect a long-term lower rate of corporation tax to apply to us. If, however, there are unexpected adverse changes to the U.K. research and development tax credit regime or the "patent box" regime, or we are unable to qualify for such advantageous tax legislation, our business, results of operations and financial condition may be adversely affected.

***Our ability to generate revenue from sales of our cell therapies and become profitable depends on our ability to progress our cell therapies through development.***

We have one cell therapy approved for commercial sale, have generated limited revenue to date from sales of our marketed cell therapy. We may never become profitable.

Our ability to generate sufficient revenue and achieve profitability depends on many factors, including:

- progressing further cell therapies through preclinical development and clinical development without substantial delays;
- demonstrating a favorable benefit (efficacy parameters): risk (safety) profile for our cell therapies;



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- obtaining regulatory approvals and marketing authorizations for our cell therapies;
- developing sustainable and scalable manufacturing and supply processes for our cell therapies to support commercial supply;
- obtaining market acceptance, pricing and reimbursement of our cell therapies as viable treatment options;
- the costs of commercializing any cell therapy including any post-marketing approval obligations; and
- the indications any cell therapy is approved in, the patient population treatable with any cell therapy and the speed with which we are able to launch a cell therapy and commercialize that cell therapy with treatment centers.

**Risks Related to the Commercialization and Marketing of Our Cell Therapies**

*Our business is, in part, dependent on the successful commercialization of TECELRA in the United States.*

TECELRA received FDA approval in August 2024. TECELRA is a genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic synovial sarcoma who have received prior systemic therapy, are positive for HLA-A\*02:01P, -A\*02:02P, -A\*02:03P, or -A\*02:06P, and negative for HLA-A\*02:05P, and whose tumor expresses the MAGE-A4 antigen as detected by an FDA-approved test. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at this point, depend on the successful commercialization of TECELRA in the U.S. Any failure to successfully commercialize TECELRA in the U.S. would have a material and adverse impact on our business.

The commercial success of TECELRA will depend on a number of factors, including the following:

- our ability to obtain any additional required capital or equivalent sources of finance to support the commercialization on acceptable terms, or at all;
- our ability to consistently manufacture TECELRA on a timely basis and sufficient to meet demand;
- our ability to activate authorized treatment centres (ATC) capable of administering TECELRA and the timing of activation of those authorized treatment centres;
- the ability of our authorized treatment centres to facilitate treatments with TECELRA given TECELRA is a novel T-cell therapy requiring patient specific administration;
- the availability of the tests required to assess for the required HLA types and antigen presentation ahead of treatment with TECELRA and the ability of third party suppliers of such tests to make those tests available when required;
- the prevalence, duration and severity of potential side effects or other safety issues that patients may experience with TECELRA;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors (including those responsible for supply of TECELRA or any raw or intermediate materials required for such supply) achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to TECELRA;
- the willingness of physicians, operators of hospitals and clinics and patients to adopt and administer TECELRA;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third-party payors for TECELRA;
- patients' ability and willingness to pay out-of-pocket for TECELRA in the absence of coverage and/or adequate reimbursement from third-party payors;
- patient demand for TECELRA;

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- the identification of patients eligible for treatment by the authorized treatment centres (including by referral from other hospitals and treatment centres) and the ability of the authorized treatment centres to progress such patients through to treatment;
- prevalence of the required HLA types and antigen within the synovial sarcoma population and the ability of the tests for HLA and antigen to function as expected;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- our ability to comply with any post marketing requirements and obligations including those imposed by the FDA as part of the authorization for TECELRA.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize TECELRA. While we have obtained regulatory approval of TECELRA in the United States, we may never be able to successfully commercialize TECELRA in the United States or receive regulatory approval of TECELRA outside the United States. Accordingly, we cannot provide assurances as to the revenue obtainable through the sale of TECELRA.

***TECELRA is approved under accelerated approval in the United States, and additional confirmatory work is required in order to maintain that approval. Inability to maintain approval or to otherwise meet the requirements imposed by the FDA will have a significant impact on our ability to commercialize TECELRA.***

TECELRA is approved under accelerated approval in the U.S. based on overall response rate and duration of response. Continued approval for this indication is contingent upon verification and description of clinical benefit in a confirmatory trial. Our ability to obtain traditional approval for TECELRA may require the conduct of additional studies and will require ongoing discussions with the FDA. Any additional work required to satisfy the conditions of accelerated approval will require additional finances, and any ability to obtain any additional required capital or equivalent sources of finance may delay or prevent our ability to maintain approval for TECELRA.

***As part of the approval of TECELRA, certain post approval requirements apply which, if not satisfied, could impact continued approval of TECELRA.***

TECELRA is subject to continuing regulation by the FDA. Failure to meet any of these requirements may result in 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.

These requirements include submissions of safety and other postmarketing information and reports, registration and listing, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. In addition, the FDA and other regulatory authorities may impose additional restrictions or require amendments to our product label after marketing approval in the event of additional adverse events with our cell therapy or of other adverse events seen with similar cell therapy products.

As part of the approval of Teclera, the FDA has imposed certain Postmarketing Commitments (“PMCs”) and Postmarketing Requirements (“PMRs”), including certain requirements to conduct additional studies under proscribed timelines. Failure to conduct these PMCs and PMRs in a timely manner could result in enforcement action from the FDA.

We and our contract manufacturers will be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs. We must also comply with requirements concerning advertising and promotion for any cell therapies for which we obtain marketing approval. Promotional communications with respect to prescription drugs, including biologics, are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product’s approved labeling. Thus, we will not be able to promote any cell therapies we develop for indications or uses for which they are not approved.

***The approval of TECELRA is limited to adult patients with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are positive for HLA-A\*02:01P, -A\*02:02P, -A\*02:03P, or -A\*02:06P, and negative for HLA-A\*02:05P, and whose tumor expresses the MAGE-A4 antigen.***

As is common for initial approval of cancer therapies, TECELRA has been approved by the FDA for use in a limited patient population, who have unresectable or metastatic synovial sarcoma and who have already received prior systemic therapy. As a result, our ability to market TECELRA is generally limited to that patient population.

The use of prior therapies or treatment for synovial sarcoma may reduce the effectiveness of our cell therapies.

***This is the first time we as an organization are marketing a product and we have limited experience as a commercial company and have never generated revenue from product sales.***

TECELRA is the first product for which we have obtained FDA approval. Accordingly, we will need to continue to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have recruited experienced commercial and medical affairs teams and we will need to continue to develop those teams and the associated support network in order to supply TECELRA on a commercial basis.

We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain suitably skilled and experienced marketing and sales personnel. This process may result in additional delays in bringing our cell therapies to market or in certain cases require us to enter into alliances with third parties in order to do so. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or even if we are able to do so, that they will result in effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the efforts of such third parties, and our revenue from cell therapy sales may be lower than if we had commercialized our cell therapies ourselves.

For TECELRA, we are using certain third parties to supplement the internal commercial facing teams. We are also using a third party distributor to supply TECELRA and third parties to provide some of the systems required to supply TECELRA and support patients prescribed with TECELRA. We are reliant on those third parties to provide the services we require in accordance with our planned timelines. If any critical third party supplier fails to provide the services as required that may result in a delay to the commercialization of TECELRA. Any inability on our part to develop inhouse sales and commercial distribution capabilities or to establish and maintain relationships with third-party collaborators that can successfully commercialize any cell therapy in the U.S. or elsewhere will have a materially adverse effect on our business and results of operations.

***As a novel cell therapy, TECELRA may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community, including referral centers.***

The use of engineered T-cells and cell therapies more generally as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. For example, the product labelling and prescribing information for TECELRA describe certain limitations of use, adverse events, and warnings and precautions, including a boxed warning related to Cytokine Release Syndrome (CRS), which may be severe or life threatening and which occurred in patients receiving TECELRA in clinical trials. Additional factors will influence whether TECELRA is accepted in the market, including:

- physicians, hospitals, cancer treatment centers and patients considering TECELRA as a safe and effective treatment;
- the potential and perceived advantages of TECELRA over alternative treatments;
- the prevalence and severity of any side effects;
- willingness of treating centers to test for the required HLA types and MAGE A4 antigen using the FDA approved tests;

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- our product labeling and prescribing information describe certain limitations of use, adverse events, and warnings and precautions;
- the cost of TECELRA in relation to alternative treatments;
- the willingness of referral centers and awareness of referral centers to refer patients to our authorized treatment centers;
- the availability of coverage, adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay for TECELRA on an out-of-pocket basis in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

The product labelling and prescribing information for TECELRA includes a boxed warning for CRS as well as other warnings and precautions. As TECELRA is used commercially, the rate and nature of adverse reactions may increase and as afamitresgene autoleucel (afami-cel) is studied in additional indications and populations, toxicities may further limit its development and use.

### ***Coverage, price flexibility, and reimbursement may be limited or unavailable in certain market segments for TECELRA.***

Successful sales of TECELRA may depend on the availability of coverage and adequate reimbursement from third-party payors. In addition, because TECELRA represents a new approach to the treatment of synovial sarcoma, we cannot accurately estimate the potential revenue from TECELRA.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient; and
- cost-effective.

Obtaining coverage and reimbursement approval of TECELRA from a government or other third-party payor is a time consuming and costly process which could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for TECELRA, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use TECELRA unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of TECELRA.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our cell therapies to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, national and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including the Affordable Care Act ("ACA") or provisions of the Inflation Reduction Act ("IRA"). Such regulatory

changes may bring prescription drug pricing reform or healthcare affordability programs that, for example, seek to lower prescription drug costs by allowing governmental healthcare programs to negotiate prices with drug companies, put an inflation cap on drug prices, and lower out-of-pocket expenses for recipients of governmental healthcare programs. We cannot predict the initiatives that may be adopted in the future.

***TECELRA represents a novel approach to treatment of synovial sarcoma that could result in heightened regulatory scrutiny.***

Use of TECELRA to treat a patient involves genetically engineering a patient's T-cells. This is a relatively novel treatment approach that carries inherent development risks including the following, any of which can result in delays to our ability to provide confirmatory evidence of TECELRA's effectiveness:

- Further development, characterization and evaluation may be required if post-marketing or clinical data suggest any potential safety risk for patients. The need to develop further assays, or to modify in any way the protocols related to TECELRA to improve safety or effectiveness, may delay the commercialization and further clinical development;
- End users and medical personnel require a substantial amount of education and training in their administration of TECELRA either to engage in confirmatory clinical trials and recruit patients or ultimately to provide TECELRA to patients;
- Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future;
- There is the potential for delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. In part for this reason, the FDA recommends a 15-year follow-up observation period for all surviving patients who receive treatment using gene therapies in clinical trials; and
- Negative results seen in third party clinical trials utilizing gene therapy products may result in regulators halting development and commercialization of our cell therapies, including TECELRA, or in requiring additional data or requirements prior to our cell therapies progressing to the next stage of development.

***Manufacturing and supply of cell therapies is complex, and if we encounter any difficulties in manufacture or supply of TECELRA or our ability to provide supply for confirmatory clinical trials commercial supply of TECELRA could be delayed or stopped.***

The process of manufacturing and administering TECELRA is complex and highly regulated. Manufacture requires the harvesting of white blood cells from the patient, isolating certain T-cells from these white blood cells, combining patient T-cells with our lentiviral delivery vector through a process known as transduction, expanding the transduced T-cells to obtain the desired dose, and ultimately infusing the modified T-cells back into the patient. As a result of the complexities, our manufacturing and supply costs are likely to be higher than those at more traditional manufacturing processes and the manufacturing process is less reliable and more difficult to reproduce.

Delays or failures in the manufacture of TECELRA (whether by us, any collaborator or our third party contract manufacturers) may result in a patient being unable to receive TECELRA or a requirement to re-manufacture which itself then causes delays in manufacture for other patients. Any delay or failure or inability to manufacture on a timely basis can adversely affect a patient's outcomes and delay the timelines for our confirmatory clinical trials and commercialization. With a commercial product delays or failure to manufacture could additionally lead to claims by patients for reimbursement or damages. Such delays or failure or inability to manufacture can result from, inter alia:

- a failure in the manufacturing process itself for example, by an error in manufacturing process (whether by us or our third party contract manufacturing organization), equipment or reagent failure, failure in any step of the manufacturing process, failure to maintain a GMP environment, failure in quality systems applicable to manufacture, sterility failures, contamination during process;
- variations in patient starting material or apheresis product resulting in less product than expected or product which is not viable, or which cannot be used to successfully manufacture a cell therapy;

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- product loss or failure due to logistical issues including issues associated with the differences between patients' white blood cells or characteristics, interruptions to process, contamination, failure to supply patient apheresis material within required timescales (for example, as a result of an import or export hold-up) or supplier error;
- inability to have enough manufacturing slots to manufacture cell therapies for patients as and when those patients require manufacture;
- inability to procure components, consumables, ingredients, or starting materials, or to manufacture starting materials (including at our U.K. vector facility), as a result of supply chain issues;
- loss of or close-down of any manufacturing facility used in the manufacture of our cell therapies. For example, we will be manufacturing TECELRA at our Navy Yard manufacturing facility. Should there be a contamination event at the facility resulting in the close-down of that facility, it would not be possible to find alternative manufacturing capability for TECELRA within the timescales required for patient supply including for commercial supply;
- loss or contamination of patient starting material, requiring the starting material to be obtained again from the patient or the manufacturing process to be re-started. In the context of commercial supply, this could result in cancellation of order for the commercial cell therapy or a claim from the patient;
- a requirement to modify or make changes to any manufacturing process. Such changes may additionally require comparability testing which then may reduce the amount of manufacturing slots available for manufacture of TECELRA. Delays in our ability to make the required modifications or perform any required comparability testing within currently anticipated timeframes or that such modifications or comparability testing, when made, will obtain regulatory approval or that the new processes or modified processes will successfully be transferred to the third party contract suppliers within currently anticipated timeframes can also impact timelines for manufacture;
- reduction or loss of the staff resources required to manufacture our cell therapies at our facilities or those of our CMOs;
- allocation of the resources, materials, and services of any collaborator or our third party contract manufacturers away from our cell therapy programs;
- reduction in available workforce to perform manufacturing processes, for example, as a result of a COVID-19 outbreak or equivalent pandemic or workforce exhibiting potential COVID-19 symptoms or equivalent pandemic symptoms, and pending receipt of test results for infection; or
- changes in the manufacturing and supply process. Any changes to the manufacturing process may require amendments to be made to regulatory applications or comparability tests to be conducted which can further delay timeframes. If TECELRA manufactured under the new process has a worse safety or efficacy profile than the prior product or the process is less reproducible than the previous process, we may need to re-evaluate the use of that manufacturing process, which could significantly delay or even result in the halting of our confirmatory clinical trials and commercialization.

***We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense as well as significant penalties if we fail to comply with regulatory requirements or experience unanticipated problems with TECELRA.***

FDA approval is accompanied by requirements to conduct surveillance to monitor the safety and efficacy of TECELRA.

Later discovery of previously unknown problems with TECELRA, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on our ability to conduct further clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on TECELRA's manufacturing processes;
- restrictions on the marketing of TECELRA;
- restrictions on product distribution;

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- requirements to conduct additional post-marketing clinical trials;
- untitled or warning letters;
- withdrawal of TECELRA from the market;
- refusal to approve pending supplements to the TECELRA that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions;
- imposition of civil penalties; or
- criminal prosecution

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could adversely impact the approval of TECELRA. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose marketing approval and we may not achieve or sustain profitability.

In addition, FDA has required us to conduct a confirmatory trial to verify the clinical benefit of TECELRA. The results from the confirmatory trial or trials may not support the clinical benefit, which could result in the approval being withdrawn.

***We may not be able to obtain marketing approvals of our cell therapies including lete-cel as broadly as planned or on the timescales we plan.***

The process of obtaining marketing approvals, both in the U.S. and in countries outside of the U.S., is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the cell therapies involved. For example, clinical trials may be required in pediatric populations before any marketing approval can be obtained, which can be time consuming and costly. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and foreign regulatory authorities also have substantial discretion in the drug and biologics approval process. The number and types of preclinical programs and clinical trials that will be required for regulatory approval varies depending on the cell therapy, the disease or condition that the cell therapy is designed to address, and the regulations applicable to any particular cell therapy. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a cell therapy's clinical development and may vary among jurisdictions, and there may be varying interpretations of data obtained from preclinical programs or clinical trials, either of which may cause delays or limitations in the approval or the decision not to approve an application.

In addition, approval of our cell therapies could be delayed or refused for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our T-cells have a beneficial benefit/risk profile for any of their proposed indications;

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- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical programs or clinical trials;
- the data collected from clinical trials of our cell therapies may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- our manufacturing processes or facilities or those of the third-party manufacturers we use may not be adequate to support approval of our cell therapies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval
- requirement for additional clinical trials ahead of the grant of any regulatory approval;
- requirement for further development or characterization of processes. For example, the potency of our cell therapies will need to be assessed by a potency assay and although we believe that our assay will be satisfactory to assess potency, the regulatory authorities may disagree which will necessitate development of a further assay or process;
- third parties we rely on being unable to meet regulatory requirements or provide information or documentation to support regulatory applications or questions from regulatory authorities. For example, we rely on a third party vector manufacturer who will be required to provide certain information to enable us to file the BLA;
- access to an approved companion diagnostic to support the launch of any cell therapy. Commercialization of our cell therapies will require approval for and access to a companion diagnostic. We are reliant on a third party for development of our companion diagnostic assay and there is no certainty that development will be possible in the timelines we require or that end regulatory approval will be available in the timelines we require; and
- data from clinical trials sponsored by third party competitors for similar cell therapy products which might impact a regulators view of the safety or efficacy profile or our cell therapies or the grant of marketing approvals to competitors ahead of any application we make for marketing approval which may preclude our ability to obtain marketing approval in the same indication unless we can show increased efficacy.

Our estimates of the patient population that may be treated by our cell therapies including afami-cel and lete-cel is based on estimates informed by published information. This information may not be accurate in relation to our cell therapies and our estimates of potential patient populations could therefore be much higher or lower than those that are actually available or possible for commercialization. In addition, these estimates are based on assumptions about the number of eligible patients which have the peptide and HLA type targeted by the applicable cell therapy. Different patient populations will present different peptides according to their specific HLA type. HLA types vary across the patient population and, due to this variability, any therapy will initially only be suitable for treatment of patients expressing the particular HLA type presenting the relevant peptide.

***The review and approval of a BLA for lete-cel may not occur on the anticipated timelines, and we cannot be certain that the FDA will grant final marketing approval.***

We are intending to submit a rolling BLA for lete-cel later in 2025 which will then be reviewed by the FDA. The FDA could refuse to grant marketing approval for lete-cel. In addition, should that review identify any additional



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requirements for information or further work, the date on which we receive marketing approval, could be significantly delayed pending provision of that information, conduct of any further work and further review by the FDA of the additional information and data from work. There is no guarantee that we will obtain marketing authorization for lete-cel within currently anticipated timelines, or that the marketing authorization will not impose further or additional requirements associated with the commercialization of lete-cel.

Approval of a BLA can be delayed or denied by the FDA for several reasons, including but not limited to those outlined above. In particular, the FDA may conclude that the data submitted in support of the BLA are insufficient to demonstrate a favorable benefit/risk profile in the proposed patient population without the submission of additional information or data, which could require the conduct of additional clinical studies and the resubmission of the BLA.

In addition the BLA approval may provide a product label with reduced scope to the label currently anticipated. This will impact the number of patients that we can treat with lete-cel.

***Development of a commercially available cell therapy process is difficult, and we may be unable to develop the process on currently anticipated timescales or at all.***

Developing a commercially viable process is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, requirements to characterize the manufacturing process, increased costs, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, loss of product, and timely availability of reagents or raw materials or contract manufacturing services or facilities. A failure to develop such a commercially viable process within anticipated timescales may prevent or delay progression of our T-cell therapies into pivotal clinical trials and ultimately commercialization. This failure to develop a timely process may result from, for example, inability to scale-up within required timelines, inability to put in place the required processes and control measures for a commercial process, inability to timely develop systems for automation of the process or failure of third parties (including vector suppliers) to put in place adequate facilities or processes to enable commercial manufacture. In addition, we may ultimately be unable to reduce the expenses associated with our cell therapies to levels that will allow us to achieve a profitable return on investment. Reduction of the costs associated with manufacture requires significant financial investment which may not be available to us.

***Following grant of marketing authorization we will be subject to ongoing regulatory obligations, which may result in significant additional expense as well as significant penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our cell therapies.***

Following approval our cell therapies, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our cell therapies will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration and listing, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. In addition regulatory authorities may impose additional restrictions or require amendments to our product label after marketing approval in the event of additional adverse events with our cell therapy or of other adverse events seen with similar cell therapy products.

We and our contract manufacturers will be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs. We must also comply with requirements concerning advertising and promotion for any cell therapies for which we obtain marketing approval. Promotional communications with respect to prescription drugs, including biologics, are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any cell therapies we develop for indications or uses for which they are not approved.

***We may not be able to develop or obtain approval for the analytical assays and companion diagnostics required for commercialization of our cell therapies including lete-cel.***

Administration of our cell therapies requires the use of an immuno-chemistry or other screening assay in which patients are screened for the presence of the cancer peptide targeted by our cell therapies. For example, prior to TECELRA being administered, patients are screened for the presence of MAGE-A4. This assay requires the identification of suitable antibodies which can be used to identify the presence of the relevant target cancer peptide. Our patients are also screened for their HLA-type as only patients with certain HLA-types can receive our cell therapies.

If safe and effective use of a biologic product depends on an *in vitro* diagnostic, such as a test to detect patients with a particular cancer peptide, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required *in vitro* companion diagnostics that are intended for use in selection of patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, which can take up to several years, for that diagnostic approval or clearance to occur simultaneously with approval of the biologic product.

We expect that, for all our cell therapies, the FDA and similar regulatory authorities outside of the U.S. will require the development and regulatory approval of a companion diagnostic assay as a condition to approval. We also expect that the FDA may require PMA supplemental approvals for use of that same companion diagnostic as a condition of approval of additional cell therapies. We rely in large part on third parties to perform these functions and develop and provide the companion diagnostics.

If we or our collaborators, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostic assays for use with any cell therapy, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, we may be unable to identify patients with the specific profile targeted by the relevant cell therapy for enrollment in our clinical trials. In addition, delay in development and approval of any companion diagnostic may also impact our ability to obtain a marketing approval for the therapeutic product and to commercialize the therapeutic product. For example, delays in the development of a companion diagnostic for detection of the NY-ESO antigen in synovial sarcoma and myxoid liposarcoma indications may result in delays to any marketing approval for lete-cel in those indications. Accordingly, further investment may be required to further develop or obtain the required regulatory approval for the relevant companion diagnostic assay, which would delay or substantially impact our ability or our collaborators' ability to conduct further clinical trials or obtain regulatory approval.

Where the FDA does not approve the use of these diagnostic assays this could delay the launch of our cell therapy products, including lete-cel.

***Obtaining and maintaining regulatory approval of our cell therapies in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our cell therapies in other jurisdictions.***

We or our collaborators may submit marketing authorization applications in multiple countries. Regulatory authorities in different countries have different requirements for approval of cell therapies with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our cell therapies in certain countries. For example, in certain jurisdictions additional clinical trials in different patient populations may be required. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our cell therapies will be harmed.

***The market opportunities for cell therapies may be limited to those patients who have failed prior treatments.***

Initial approval of new cancer therapies may be limited to what is referred to as third-line use. Third-line treatment is the third type of treatment following initial, or first-line, treatment and second-line treatment, which is given when first-line treatment does not work or ceases working. However, cancer therapies may be used from the point at which cancer is detected in its early stages (first-line) onward. Whenever the first-line therapy fails or the process is unsuccessful, second-line therapy may be administered, such as additional rounds of chemotherapy, radiation and antibody drugs or a combination of these treatments. If second-line therapies fail, patients are generally given the

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opportunity to receive third-line therapies, which tend to be more novel therapies. Our current clinical trials generally require that patients have received chemotherapy prior to enrollment and are primarily directed to third-line use. Depending upon the outcome of current trials, we or our collaborators may conduct future clinical trials using cell therapies for first-line therapy, but clinical trials might not be approved or if approved such trials might not lead to regulatory approval. If our cell therapies only receive third-line or second-line approval, the patient population into which we or our collaborators can supply our cell therapies will be significantly reduced, which may limit commercial opportunities.

In addition, our patient population may be derived from those who have previously failed checkpoint therapy, which may result in tumor resistance mechanisms which also impart resistance to our cell therapies and hence may reduce the effectiveness of our cell therapies.

***We currently have a limited marketing and sales organization and as an organization have no experience in marketing products.***

As an organization, we have never marketed or supplied commercial pharmaceutical or biologic products or therapies. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We have recruited a sales and field force and will need to continue to hire and develop the sales function and associated support network for the supply of our cell therapies, including TECELRA and lete-cel on a commercial basis. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain suitably skilled and experienced marketing and sales personnel. To expand commercialization or to commercialize outside of the US, additional resources or alliances with third parties will be required. There can be no assurance that we will be able to establish or maintain any required arrangements, or even if we are able to do so, that they will result in effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from cell therapy sales may be lower than if we had commercialized our cell therapies ourselves.

For afami-cel we are using certain third parties to supplement the internal commercial facing teams. We are also using a third party distributor to supply afami-cel and third parties to provide some of the systems required to supply a cell therapy. We are reliant on those third parties to provide the services we require in accordance with our planned timelines. If any critical third party supplier fails to provide the services as required that may result in a delay to the commercialization of afami-cel. Any inability on our part to develop in-house sales and commercial distribution capabilities or to establish and maintain relationships with third-party collaborators that can successfully commercialize any cell therapy in the U.S. or elsewhere will have a materially adverse effect on our business and results of operations.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our cell therapies.***

We face an inherent risk of product liability as a result of the clinical testing of our cell therapies and our ongoing manufacture of cell therapies and will face an even greater risk upon any commercialization, including commercialization of afami-cel. For example, we may be sued if any of our cell therapies causes or is perceived to cause injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our cell therapies. Even a successful defense would require significant financial and management resources and, regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our cell therapies;
- injury to our reputation;

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- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our cell therapies; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable price to protect against potential product liability claims could also prevent or inhibit the commercialization of our cell therapies. We clinical trial insurance coverage, products and services liability insurance and public liability insurance, which are all capped at certain levels. These levels 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.

***Even if we or our collaborators obtain regulatory approval of our cell therapies, they may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.***

The use of engineered T-cells and cell therapies more generally as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Additional factors will influence whether our cell therapies are accepted in the market, including:

- the clinical indications for which our cell therapies are approved;
- physicians, hospitals, cancer treatment centers and patients considering the cell therapies as a safe and effective treatment;
- the potential and perceived advantages of our cell therapies over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or prescribing information requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our cell therapies as well as competitive products;
- the cost of treatment in relation to alternative treatments;

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- the availability of coverage, adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay for cell therapies on an out-of-pocket basis in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors in our manufacturing process, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance of cell therapies. If our cell therapies are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our cell therapies achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our cell therapies, are more cost effective or render our cell therapies obsolete.

### ***Coverage, price flexibility, and reimbursement may be limited or unavailable in certain market segments for cell therapies.***

Successful sales of cell therapies, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. In addition, because cell therapies represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from cell therapies. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a cell therapy from a government or other third-party payor is a time-consuming and costly process which could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given cell therapy, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use cell therapies unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the cell therapy.

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In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our cell therapies to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a cell therapy. In addition, market acceptance and sales of our cell therapies will depend significantly on the availability of coverage and adequate reimbursement from third-party payors for the cell therapies and may be affected by existing and future health care reform measures.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, national and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including the Affordable Care Act (“ACA”) or provisions of the Inflation Reduction Act (“IRA”). Such regulatory changes may bring prescription drug pricing reform or healthcare affordability programs that, for example, seek to lower prescription drug costs by allowing governmental healthcare programs to negotiate prices with drug companies, put an inflation cap on drug prices, and lower out-of-pocket expenses for recipients of governmental healthcare programs. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for cell therapies, if we or our collaborators obtain regulatory approval;
- our or our collaborators’ ability to set a price that is fair for our cell therapies;
- our or our collaborators’ ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may adversely affect our future profitability.

### ***Our cell therapies for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated 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 existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product or “reference” is approved under a BLA. On March 6, 2015, the FDA approved the first biosimilar product under the BPCIA. However, the law is complex and is still being interpreted and implemented by the FDA and as a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

There is a risk that the FDA will not consider each of our cell therapies to be entitled to 12-year reference product exclusivity, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own full BLA, rather than via the abbreviated biosimilar pathway. Moreover, the extent to which a biosimilar, once approved, will be

substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological drug products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Foreign countries also have abbreviated regulatory pathways for biosimilars and hence even where the FDA does not approve a biosimilar biologic, a biosimilar could be approved using an abbreviated regulatory pathway in other markets where our cell therapies are approved and marketed.

#### **Risks Related to the Development of Our Cell Therapies**

***Our cell therapy products require significant additional clinical testing before we can seek regulatory approval and begin commercialization.***

Our cell therapies may not achieve regulatory approval or proceed to the next stage of development. All of our cell therapies other than TECELRA and lete-cel require further development before a BLA can be filed with any regulatory authority to permit commercialization. Results seen in early clinical trials or pre-clinical testing, may not be predictive of the data we will obtain in our clinical trials including later phase clinical trials. Negative results in any cell therapy clinical program may also impact our ability to continue with clinical development of other similar cell therapies. Although each cell therapy may target a different cancer peptide or protein, the underlying technology platform and other aspects of our clinical programs are the same or substantially similar for many of our cell therapies. Accordingly, a failure or delay in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other cell therapies.

***The data produced in preclinical testing and clinical trials for our preclinical and clinical-stage cell therapies is at an early stage, and future data may not support continued progression of any of these therapies through development.***

As such, the data is initial data, and there is no assurance that any responses will persist, that we will see responses in any other patients or that such patients will not suffer severe adverse events which may result in a delay or halt to any clinical trial. Further data may be required in order to progress cell therapies to the next stage of development. Negative results in one clinical trial may also impact ability to proceed with development in other clinical trials given the common technology platform and similarity of other aspects of our clinical programs.

Like other biologic products, we expect there may be greater variability in results for cell therapies which are administered on a patient-by-patient basis than for “off-the-shelf” products, like many other biologics. There is typically an extremely high rate of attrition from the failure of any products proceeding through clinical trials. Cell therapies in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical programs and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most biologic candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may therefore be unsuccessful in demonstrating the required efficacy and safety profile from the performance of any of our clinical programs.

We are aware that certain patients do not respond to our cell therapies and that other patients may relapse or cease to present the peptide being targeted by such cell therapies. The percentage of the patient population in which these events may occur is unknown, but the inability of patients to respond and the possibility of relapse may impact our ability to conduct clinical trials, to obtain regulatory approvals, if at all, and to successfully commercialize any cell therapies.

***We may not be able to commence additional clinical trials for cell therapies on the timeframes we expect.***

Progression of new cell therapies into clinical trials is inherently risky and dependent on the results obtained in preclinical programs, the results of other clinical programs and any other activities which may impact our ability to commence clinical trials, for example, availability of manufacturing process and components. If any issues are identified during any cell therapy development, we may experience significant delays in development of pipeline candidates

including our PRAME and CD70 programs. We have paused all spend on the PRAME and CD70 programs which may delay progression of these programs through preclinical development and into clinical development. This may also impact our ability to achieve certain financial milestones, for and the expected timeframes to market any of our cell therapies.

The FDA or other regulatory authorities may not approve any IND (or equivalent application) for any of our future cell therapies, or for new indications for our cell therapies already in clinical trials, or may require amendments to existing protocols (including as a result of the COVID-19 pandemic or other similar pandemics). For example, we amended the protocols for our clinical trials in response to reported serious adverse events (“SAEs”) of prolonged serious pancytopenia in our clinical trials. Such amendments and updates may delay our clinical trials, may require changes or resubmission of our INDs, or may result in or be related to a halt in our planned or contemplated clinical trials.

We conduct clinical trials at sites in the U.K. and European Union. This requires gaining the approval of country specific review bodies for GMO application and Clinical Trial Application (“CTA”). As this is not a harmonized process, the requirements can vary considerably, and delays can be incurred at a country level. For example, the information required in relation to manufacturing processes or assays may differ between countries and may require additional testing to be conducted in order for approval to be obtained.

***T-cell therapy is a novel approach to cancer treatment that creates significant increased risk in terms of side-effect profile.***

Development of a pharmaceutical or biologic therapy or product has inherent risks based on differences in patient population and responses to therapy and treatment. The mechanism of action and impact on other systems and tissues within the human body following administration of our cell therapies is complex and not completely understood, which means that we cannot predict the long-term effects of treatment with any of our cell therapies (whether by us or a collaborator). In addition, it is not possible for any pre-clinical safety package to completely identify all potential safety risks. For example, there is a risk that the target (or similar) peptide to which any T-cell is directed may be present in both patients’ cancer cells and other non-cancer cells and tissues. Cross-reactivity or allo-reactivity (binding to peptides presented on other HLA types) could also occur where the affinity-enhanced engineered TCR contained within any cell therapy including our T-cells binds to peptides presented by HLAs other than the HLA type for which the relevant TCR was developed. Should any of these cross-reactivities occur, patients may suffer a range of side effects associated with the T-cell binding to both the cancer cells and/or other cells and tissues and such side effects could cause patient death. The extent of these side effects will depend on which cells and tissues are affected as well as the degree to which the target (or similar) peptide is expressed in these cells and tissues.

Any unacceptable toxicities arising in ongoing clinical programs could result in suspension or termination of those clinical programs. The more serious adverse events (“SAEs”) that are reported the greater the risk of suspension or termination of clinical programs, even where the SAEs are unrelated to each other or to our cell therapies. Our patients undergo lymphodepletion prior to receiving our cell therapies which leaves them immuno-compromised for a period of time after the lymphodepletion and increases their risk of contracting other unrelated diseases or pathogens including COVID-19. The treatment regimen used in our protocols, in particular the use of chemotherapy, also carries an inherent risk of cytopenia (including pancytopenia), where blood cell levels reduce to lower than normal. If blood cell levels do not recover sufficiently the patient may suffer serious adverse events, which may even be life threatening. There have been multiple events of pancytopenia as well as SAEs similar to those reported across our clinical trials; these are multifactorial in etiologies and could result in regulatory authorities imposing a hold on one or more clinical programs whilst the events are investigated further. Serious adverse events seen with other immunotherapy products, such as the severe cytokine release syndrome (“CRS”) and neurotoxicity events observed with CD19-directed CAR T-cell treatments, may also occur at any stage of the clinical program. Further, following infusion of any of our T-cells, there may be a transient inflammatory reaction of the disease to the treatment. Symptoms in any given subject would be dependent on the location and other characteristics of their tumor. For example, subjects with lung tumors may experience dyspnea. Cardiac toxicities may be observed in patients with pre-existing cardiac or pericardial masses. These inflammatory reactions and related symptoms may be mild and self-limited, but can be severe, potentially life-threatening and require medical intervention.



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Any side effects may also result in the need to perform additional trials, which will delay regulatory approval for such cell therapies and require additional resources and financial investment to bring the relevant cell therapy to market.

Use of cell therapies in combination with other third party products or therapies may increase or exacerbate side effects that have been seen with our cell therapies alone or may result in new side effects that have not previously been identified with our cell therapies alone. Any undesirable side effects seen in combination trials may affect our ability to continue with and obtain regulatory approval for the combination therapy, but may also impact our ability to continue with and obtain regulatory approval for our cell therapies alone.

Summary information on adverse events (“AEs”) seen in relation to each of our cell therapies are provided below

### *Afami-cel:*

- As of December 27, 2024, 187 patients received at least one dose of transduced cells of afami-cel across multiple studies. 167 (89.3%) patients experienced adverse events. Adverse events occurring in >10% of subjects considered by investigators to be at least possibly related to afami-cel include CRS, pyrexia, neutropenia/neutrophil count decreased, fatigue, leukopenia/WBC decreased, sinus tachycardia/tachycardia, lymphopenia/ lymphocyte count decreased, nausea, hypotension, rash, thrombocytopenia/platelet count decreased, chills, anaemia/RBC, hypophosphataemia and headache.
- Serious adverse event (SAEs), considered by investigators to be at least possibly related to afami-cel were reported for 47 (25.1%) subjects under the program. These events include empyema, sepsis, cytokine release syndrome, pleural effusion, pneumothorax, pulmonary embolism, pyrexia, anemia, aplastic anemia, pancytopenia, cerebrovascular accident, encephalopathy, neurotoxicity, arrhythmia, alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased, platelet count decreased, lymphoproliferative disorder, deep vein thrombosis, superior vena cava occlusion, acute kidney injury, arthralgia, pulmonary hemorrhage, adrenal insufficiency, white blood cell count decreased, tumor pain, infusion related reaction, hypercalcemia, COVID-19 pneumonia, respiratory failure, multiple organ dysfunction syndrome, cardiac arrest, and rash. Three of these subjects have had treatment related fatal SAEs: one patient experienced pancytopenia/aplastic anemia, one patient experienced cardiac arrest, and the other experienced a cerebrovascular accident (stroke).
- Eleven subjects experienced long term follow up events. The events were thrombocytopenia/Platelet count decreased, pneumonia, sepsis, anemia/RBC decreased, bacteraemia, Covid-19, cerebral thrombosis, hemiparesis, herpes zoster, hyperthyroidism, lung disorder, pain, oral fungal infection and myelodysplastic syndrome.

### *ADP-A2M4CD8 (uza-cel):*

- As of November 22, 2023, in the SURPASS study, there have been 46 patients treated with ADP-A2M4CD8 monotherapy. The adverse events occurring in >10% of patients treated with ADP-A2M4CD8 monotherapy (n=46) and considered by investigators to be at least possibly related to ADP-A2M4CD8 include CRS, neutropenia/neutrophil count decreased, fatigue, anemia/red blood cell count decreased, thrombocytopenia/platelet count decreased, immune effector cell-associated neurotoxicity syndrome (ICANS), pleural effusion, pyrexia, rash, dyspnea, hypoxia, leukopenia/ white blood cell count decreased, sinus tachycardia/tachycardia, decreased appetite, febrile neutropenia, and lymphopenia/ lymphocyte count decreased.
- SAEs, considered by investigators to be at least possibly related to ADP-A2M4CD8 monotherapy, were reported for 23 (50.0%) patients in the study. These events include CRS, ICANS, drug reaction with eosinophilia and systemic symptoms (DRESS Syndrome), rash, hypoxia, dyspnea, plueral effusion, device related infection, pneumonia, sepsis, anemia, pancytopenia, pyrexia, myocarditis,

small intestinal obstruction, infusion related reaction, blood creatinine increased, tumor lysis syndrome, and myositis. Three of these patients had treatment-related fatal SAEs (pancytopenia, CRS, and myositis). In addition, there have been 10 patients treated with nivolumab in combination with ADP-A2M4CD8. Nine out of 10 subjects had AEs related to T-cell infusion, including CRS, rash, pyrexia, fatigue, C-reactive protein increased, decreased appetite, febrile neutropenia, headache, hypotension, ICANS, infusion related reaction, lymphopenia/lymphocyte count decreased, sinus tachycardia/tachycardia, stomatitis and thrombocytopenia/platelet count decreased. Febrile neutropenia, fatigue, and hypotension were the only AEs related to T-cell infusion and nivolumab.

*Lete-cel:*

- As of January 27, 2023, 198 patients out of 199 patients experienced treatment emergent adverse events. Adverse events (AEs) occurring in >10% of subjects considered by investigators to be at least possibly related to Lete-cel include cytokine release syndrome (CRS), neutropenia/neutrophil count decreased, leukopenia/white blood cell decreased, thrombocytopenia/platelet count decreased, anaemia/red blood cell count decreased, pyrexia, rash/rash maculo-papular, fatigue, diarrhea, nausea, febrile neutropenia, hypophosphatemia, alanine aminotransferase increased, tachycardia, dyspnoea, decreased appetite, aspartate aminotransferase increased, lymphopenia/lymphocyte count decreased, hypotension, hypokalaemia, alopecia, chills, hypocalcemia, headache, hyponatremia, hypoalbuminemia, cough, vomiting, hypomagnesaemia, pruritus, blood alkaline phosphatase increased.
- Serious adverse event (SAEs), considered by investigators to be at least possibly related to lete-cel, were reported for 92 (46%) subjects under the program. These events include CRS, febrile neutropenia, neutropenia/neutrophil count decreased, pyrexia, rash/rash maculo-papular, thrombocytopenia/platelet count decreased, anemia/RBC decreased, dyspnea, hypotension, pancytopenia, unspecified GVHD – other (lung, bone marrow, not specified), pleural effusion, acute GVHD –other (lung, bone marrow, not specified), device related infection, diarrhoea, nausea, bacteraemia, blood bilirubin increased, bone marrow failure, cardiac arrest, dermatitis exfoliative generalized, Guillain-Barre syndrome, hemorrhage intracranial, hyponatremia, hypoxia, immune effector cell-associated neurotoxicity syndrome (ICANS), leukopenia/white blood cell decreased, neutropenic sepsis, pericardial effusion, pneumonitis, staphylococcal infection, and tumor pain.
- As of January 27, 2023, one hundred and eighty-two patients treated with lete-cel were in long term follow-up (LTFU) phase. In 90 safety population, potential Grade  $\geq 3$  delayed AEs includes pulmonary alveolar hemorrhage, BK virus infection, febrile neutropenia, herpes zoster, Guillain-Barre syndrome, peripheral motor neuropathy, and peripheral sensory neuropathy.
- As of 27 Jan 2025, the IGNUYTE study is closed to enrollment; the LTFU study is still ongoing. There has been no significant safety information received since 27 Jan 2023.

***We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.***

Any delay in our clinical trials will impact our ability to obtain clinical data from those trials and our ability to progress our business along anticipated timelines and to raise capital. Delays in clinical trials can also increase the costs incurred in performing those clinical trials or necessitate a need to initiate additional clinical trial sites. Our ability to progress our clinical trials is dependent on a number of factors including:

- Finding clinical sites prepared to carry out the relevant clinical trials, screening of patients by the clinical sites, recruitment of patients both in terms of number and type of patients and general performance of the relevant clinical site.

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- The ability of our clinical sites to recruit patients on the timelines we expect. It can be difficult for clinical sites to find patients that express both the required HLA-type (if required) and required antigen type and which also meet the inclusion criteria for our clinical trials
- The patient population in which any required peptide antigen is presented. The patient population may be lower than expected which will increase the timescales required to find and recruit patients into the applicable clinical trial. Screening of a large number of patients is required to identify HLA and tumor antigen positive patients for all of our clinical trials with our engineered T-cells.
- Our ability to select, initiate and activate clinical sites on the timelines we expect. Selection and activation of clinical trial sites can take a long period of time and includes requirements to assess the clinical trial site, obtain IRB approval of clinical trial protocols, negotiate and execute clinical trial agreements and educate study staff to enable them to carry out the clinical trial.
- Any requirement to change clinical trial design as the clinical trial progresses. It is also difficult to predict whether changes may be required to any clinical trial design as our clinical trials progress. The need to make changes to any clinical trial design can result in delays to the performance of that clinical trial whilst any changes are approved by the FDA or other relevant authority and implemented at applicable clinical trial sites.
- Any competition for patients at our clinical sites. Many of our clinical trial sites have multiple clinical trials ongoing which compete for patients in any specific indication. We may have to wait before treating patients while patients complete existing clinical trials or receive other treatment therapies for their cancer. Moreover, because our cell therapies represent a departure from more commonly used methods for cancer treatment, potential patients and their physicians may opt to use conventional therapies, such as chemotherapy and hematopoietic cell transplantation, rather than enrollment in any of our current or future clinical trials. This may also mean we cannot recruit patients at a suitable time in their disease progression.
- Any change in the standard of care for patients. Where standard of care for patients changes clinical sites may no longer be prepared to continue with any clinical trial or require amendments to agreed protocols for clinical trials. Such circumstances can lead to the suspension of the relevant clinical trial at a site, inability to recruit further patients at that clinical site or a requirement to amend the protocol, all of which will delay or potentially halt progression of a cell therapy through clinical trials.
- Any country-specific requirement. In certain countries, additional data, studies or documentation may be required ahead of any clinical trial starting. For example, comparability studies may be required in relation to any changes in manufacturing process and the extent of these comparability studies can vary between different countries. This can result in delays to the start of any clinical trials in those countries and lead to increased research and development being required ahead of the start of those clinical trials.
- The severity of the disease we are trying to treat and the type of patient we are trying to recruit. For many of our clinical trials patients have received numerous prior therapies and have few or no other remaining treatment options. Given the late stage of their disease the patients also tend to be very ill and hence require treatment quickly and have the potential for increased SAEs following treatment. Depending on the protocol it can be difficult to find patients that meet the inclusion requirements for our clinical trials and can wait for manufacture of our cell therapy products.
- The clinical trial protocol design and in particular the inclusion and exclusion requirements applicable to the clinical trial.

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- Patient referral practices. It is common for investigators or physicians not to refer patients to other investigators or physicians either within their own clinical sites or to other clinical sites. This increases the number of clinical sites which have to be initiated in order to recruit patients to our clinical trials.
- Availability of reimbursement from insurance companies. The availability of reimbursement for patients to participate in clinical trials can impact on their ability to enroll in our clinical trials.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in, and have resulted in, increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our cell therapies.

Certain of our clinical trials include dose escalation studies in which the dose of cell therapies administered to patients is varied or initial studies in which the pre-treatment regimen may be varied, for example, a regimen with and without fludarabine. The outcome of such dose escalation or initial studies will inform the clinical study going forward. However, the need to carry out dose escalation or other initial studies may result in delays in data from such clinical programs while the most suitable dose or regimen is assessed. For example, the trial design for our cell therapy trials includes dose escalation and therefore efficacy data may not be obtained from initial patients treated in such studies during the dose escalation phase.

### ***Our cell therapies represent a novel approach to cancer treatment that could result in heightened regulatory scrutiny and delays in clinical development.***

Use of any of our cell therapies to treat a patient involves genetically engineering a patient's T-cells. This is a novel treatment approach that carries inherent development risks including the following, any of which can result in delays to our ability to develop our cell therapies:

- Further development, characterization and evaluation may be required at any point in the development of any cell therapy where clinical or preclinical data suggest any potential safety risk for patients. The need to develop further assays, or to modify in any way the protocols related to our cell therapies to improve safety or effectiveness, may delay the clinical program, regulatory approval or commercialization, if approved at all, of any cell therapy.
- End users and medical personnel require a substantial amount of education and training in their administration of cell therapies either to engage in clinical trials and recruit patients or ultimately to provide cell therapies to patients once our cell therapies have been approved.
- Regulators may be more risk averse or require substantial dialogue and education as part of the normal regulatory approval process for each stage of development of any cell therapy. Many regulators have additional requirements or processes relating to cell therapy products which need to be addressed during development. To date, only a limited number of gene therapy products have been approved in the U.S. and EU. Consequently, it is difficult to predict and evaluate what additional regulatory hurdles may apply to the development of our cell therapies and whether additional investment, time or resources will be required to overcome any such hurdles.
- Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future.
- Random gene insertion associated with retrovirus-mediated genetically modified products, known as insertional oncogenesis, could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells. Insertional oncogenesis was seen in early gene therapy studies conducted outside of the U.S. in 2003 although these studies utilized a murine gamma-retroviral vector rather than a lentiviral vector.

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- Although our viral vectors are not able to replicate, there may be a risk with the use of retroviral or lentiviral vectors that they could undergo recombination and lead to new or reactivated pathogenic strains of virus or other infectious diseases.
- There is the potential for delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. In part for this reason, the FDA recommends a 15-year follow-up observation period for all surviving patients who receive treatment using gene therapies in clinical trials.
- Clinical trials using genetically modified cells may be subject to additional or further regulatory processes, for example, by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or RAC or the need to apply for a specific applications relating to the use of Genetically Modified Organism application in the EU. These additional processes may delay or impede the initiation of a clinical trial.
- Increased risk to patient safety caused by the need to lymphodeplete patients prior to administration of our cell therapies including in circumstances in which there is a heightened safety risk or in which medical resources could be prioritized elsewhere, for example, during a pandemic such as COVID-19.
- Negative results seen in third party clinical trials utilizing gene therapy products may result in regulators halting development of our cell therapies or in requiring additional data or requirements prior to our cell therapies progressing to the next stage of development. For example, regulators could require changes to be made to our clinical trial protocols or increase requirements for dose escalation studies as part of our clinical trial protocols.

### ***Our clinical trials may fail to demonstrate adequately the safety and efficacy of any cell therapies which would prevent or delay regulatory approval and commercialization.***

There is a risk in any clinical trial that side effects from cell therapies will require a hold on, or termination of, clinical programs or further adjustments to clinical programs in order to progress any cell therapy. Our cell therapy must demonstrate an acceptable benefit/risk profile in its intended patient population and for its intended use. The benefit/risk profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease and/or an improvement in survival. For example, response rates from the use of our cell therapies may not be sufficient to obtain regulatory approval unless we show an adequate duration of response.

The regulatory authorities (including the FDA) may issue a hold on our clinical trials as a result of safety information and data obtained in third party clinical trials or in relation to third party products. Any such hold will require addressing by us and will inevitably delay progression of the clinical trials concerned, if such clinical trials progress at all.

In addition, even if such trials are successfully completed, the FDA or foreign regulatory authorities may not interpret the results as we do. Accordingly, more trials may be required before we can submit any cell therapy for regulatory approval or additional data may be required in order to obtain full approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing authorization application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials and development in support of potential approval of our cell therapies. We cannot predict whether any of our cell therapies will satisfy regulatory requirements at all or for indications in which such cell therapies are currently being evaluated as part of any clinical programs.

### ***Clinical trials are expensive, time-consuming and difficult to implement.***

Clinical trials, depending on the stage, can be costly as well as difficult to implement and define, particularly with technologies that are not tried and tested, such as our cell therapies. These factors can lead to a longer clinical development timeline and regulatory approval process, including a requirement to conduct further or more complex

clinical trials in order to obtain regulatory approval. Regulatory authorities may disagree with the design of any clinical program, and designing an acceptable program could lead to increased timeframes for obtaining of approvals, if any. In addition, progression of clinical trials depends on the ability to recruit suitable patients to those trials and delay in recruiting will impact the timeframes of such clinical trials and as a result the timeframes for obtaining regulatory approval, if any, for the relevant cell therapy.

In particular, eligible patients may need to be screened for the target peptide and HLA type, which may reduce the number of patients who can be recruited for any clinical program. The ability to administer cell therapies to patients in accordance with set protocols for the clinical trials and the results obtained depends on patient participation for the duration of the clinical trial, which many of these patients are unable to do because of their late-stage cancer and limited life expectancy.

***Validation of our cell therapies requires access to human samples which we may be unable to obtain or, if they can be obtained, that the terms under which they are provided will be favorable to us.***

Certain of the steps involved in validating and carrying out safety testing in relation to our cell therapies require access to human samples (e.g., tissues samples or cell samples) from third parties. Such samples may be obtained from universities or research institutions and will often be provided subject to certain terms and conditions. We may not be able to obtain samples in sufficient quantities to enable preclinical testing in sufficient quantities for planned activities. In addition, the terms under which such samples are available may not be acceptable to us or may restrict our use of any generated results or require us to make payments to the third parties.

***Our cell therapies and their application are not fully scientifically understood and are still undergoing validation and investigation.***

Our cell therapies and their potential associated risks are still under investigation. Our cell therapies may not work in the way that we currently anticipate and affinity modification of the receptors within T-cells or other cellular therapies may not produce the anticipated enhancements in activity. For example, there is a potential risk that, given that the TCR chains in our T-cells are produced separately and then assembled within patient T-cells into full TCRs, the TCR chains from both transduced and naturally occurring T-cells could be assembled into an unintended end TCR due to mispairing of TCR chains, which could create unknown recognition and cross-reactivity problems within patients. Although this phenomenon has not been reported in humans, it remains a theoretical risk for our cell therapies and other similar cell therapies and is still being studied and investigated. This could delay regulatory approval, if any, for the relevant cell therapy. To the extent that any mispairing is identified, either in our or our competitors' clinical trials, additional investment may be required in order to modify relevant cell therapies and to further assess and validate the risk of such mispairing to patients. Following modification of the relevant cell therapy, such modified cell therapy may not remain suitable for patient treatment and may not eliminate the risk of mispairing of TCR chains and regulatory approval may not be obtained on a timely basis or at all in relation to such modified cell therapy. The occurrence of such events would significantly harm our business, prospects, financial condition and results of operations.

***We may not be able to identify and validate additional target peptides or isolate and develop affinity-enhanced TCRs or other cell therapy candidates that are suitable for validation and further development.***

The success of our cell therapies depends on both the identification of target peptides presented on cancer cells, which can be bound by our cell therapy products, and isolation and affinity enhancement of receptors including TCRs, which can be used to treat patients if regulatory approval is obtained. Any failure to identify and validate further target peptides will reduce the number of potential cell therapies that we can successfully develop, which in turn will reduce the commercial opportunities available to us and increase our reliance on our existing cell therapies. Delays in our ability to identify and develop target peptides and cell therapies, including as caused by lack of financing, pandemics such as COVID-19 or similar, may also impact our ability to progress development of programs and obtain additional funds to support our business.

We may not develop new cell therapy candidates for which the safety and efficacy profiles enable progression to and through preclinical testing and into clinical development. Failure to identify further candidates for progression into preclinical testing and clinical programs will significantly impact our pipeline of cell therapies and also increase our reliance on the cell therapies currently in clinical development. If resources become limited or if we fail to identify suitable target peptides, receptors including TCRs or affinity-enhanced receptors, our ability to submit INDs for further cell therapies may be delayed or never realized, which would have a materially adverse effect on our business.

***Development of an “off-the-shelf” cell therapy takes a considerable amount of time and such development may not be successful.***

We have a platform process which may enable us to treat patient populations with an “off-the-shelf” product. However, our research program may not be successful, might not be carried out within the timescales currently anticipated, or even if successful might not result in a cell therapy that can be used to treat patients or achieve a profitable return on investment. In particular the various cell lines developed during this process will need to be properly characterized and produced in accordance with regulatory requirements and this development process can take a significant amount of time and resource to ensure that any process or cell lines can be used for the production of clinical stage and ultimately commercial stage products. It is not known at this time whether the cell therapy candidates resulting from the process will have a similar profile of activity to our existing cell therapy products or whether such cell therapy candidates will be safe to administer to patients. Delays may occur at any part of the process, including obtaining results during development that necessitate a requirement to repeat or modify steps in the process. The regulatory requirements for an off-the-shelf product are not known and regulators could require significant additional development steps, which in turn could delay our ability to enter clinical development with our off-the-shelf cell therapies.

**Risks Related to the Manufacture and Supply of Our Cell Therapies**

***Manufacturing and supply of cell therapies is complex, and if we encounter any difficulties in manufacture or supply of cell therapies our ability to provide supply of our cell therapies for clinical trials or for commercial purposes could be delayed or stopped.***

The process of manufacturing and administering cell therapies is complex and highly regulated. The manufacture of cell therapies requires the harvesting of white blood cells from the patient, isolating certain T-cells from these white blood cells, combining patient T-cells with our lentiviral delivery vector through a process known as transduction, expanding the transduced T-cells to obtain the desired dose, and ultimately infusing the modified T-cells back into the patient. As a result of the complexities, our manufacturing and supply costs are likely to be higher than those at more traditional manufacturing processes and the manufacturing process is less reliable and more difficult to reproduce.

Delays or failures in the manufacture of cell therapies (whether by us, any collaborator or our third party contract manufacturers) can result in a patient being unable to receive their cell therapy or a requirement to re-manufacture which itself then causes delays in manufacture for other patients. Any delay or failure or inability to manufacture on a timely basis can adversely affect a patient’s outcomes and delay the timelines for our clinical trials. With a commercial product delays or failure to manufacture could additionally lead to claims by patients for reimbursement or damages. Such delays or failure or inability to manufacture can result from:

- a failure in the manufacturing process itself for example, by an error in manufacturing process (whether by us or our third party contract manufacturing organization), equipment or reagent failure, failure in any step of the manufacturing process, failure to maintain a GMP environment, failure in quality systems applicable to manufacture, sterility failures, contamination during process;
- a lack of reliability or reproducibility in the manufacturing process itself leading to variability in end manufacture of cell therapy. Should the process be unreliable, the relevant regulatory agency (such as the FDA in the U.S.) may place a hold on a clinical trial or request further information on the process which could in turn result in delays to the clinical trials;

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- variations in patient starting material or apheresis product resulting in less product than expected or product which is not viable, or which cannot be used to successfully manufacture a cell therapy;
- product loss or failure due to logistical issues including issues associated with the differences between patients' white blood cells or characteristics, interruptions to process, contamination, failure to supply patient apheresis material within required timescales (for example, as a result of an import or export hold-up) or supplier error;
- inability to have enough manufacturing slots to manufacture cell therapies for patients as and when those patients require manufacture;
- inability to procure components, consumables, ingredients, or starting materials, or to manufacture starting materials (including at our U.K. vector facility), as a result of supply chain issues;
- loss of or close-down of any manufacturing facility used in the manufacture of our cell therapies. For example, we will be manufacturing afami-cel at our Navy Yard manufacturing facility. Should there be a contamination event at the facility resulting in the close-down of that facility, it would not be possible to find alternative manufacturing capability for afami-cel within the timescales required for patient supply including for commercial supply. In addition, as with many pharmaceutical manufacturing facilities, the facility will have periods of time within which it cannot be used for manufacture of patient product to enable routine checks to be performed on the facility;
- loss or contamination of patient starting material, requiring the starting material to be obtained again from the patient or the manufacturing process to be re-started. In the context of commercial supply, this could result in cancellation of order for the commercial cell therapy or a claim from the patient;
- a requirement to modify or make changes to any manufacturing process. Such changes may additionally require comparability testing which then may reduce the amount of manufacturing slots available for manufacture of our cell therapies. Delays in our ability to make the required modifications or perform any required comparability testing within currently anticipated timeframes or that such modifications or comparability testing, when made, will obtain regulatory approval or that the new processes or modified processes will successfully be transferred to the third party contract suppliers within currently anticipated timeframes can also impact timelines for manufacture;
- reduction or loss of the staff resources required to manufacture our cell therapies at our facilities or those of our CMOs;
- allocation of the resources, materials, and services of any collaborator or our third party contract manufacturers away from our cell therapy programs;
- reduction in available workforce to perform manufacturing processes, for example, as a result of a pandemic, such as the COVID-19 outbreak or similar pandemic or workforce exhibiting potential pandemic symptoms, and pending receipt of test results for infection;
- increased country-specific requirements. For example, our current manufacturing site is in the U.S. and this means that for patients outside of the U.S. there is a need to transfer patient-specific apheresis material from clinical sites in Europe to the manufacturer in the U.S., for the patient product to be converted into our end cell therapy product, for that product to be released for use in Europe and then for that cell therapy product to be transported back to the site in Europe for administration to the patient. The supply and manufacturing chain required to achieve this is very complex and could be subject to failures at any point
- inability to engage with third party manufacturers within the timelines required to support planned activities. For example, we are using a series of third party contract manufacturing organizations to



manufacture the vector and cell therapy for lete-cel. It takes time to set up and finalize manufacturing with a new vendor and there is no guarantee that we will be able to achieve that within currently planned timelines or that once set-up the manufacturing process will provide comparable to that used in prior clinical trials; and

- changes in the manufacturing and supply process. As our cell therapies progress through preclinical programs and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing and administration process will be altered in an effort to optimize processes and results. We have already identified some improvements to our manufacturing and administration processes, but these changes may not achieve the intended objectives, may not be transferable to third parties or able to be used at larger scales and could cause our cell therapies to perform differently or affect the results of planned clinical trials or other future clinical trials. Any changes to the manufacturing process may require amendments to be made to regulatory applications or comparability tests to be conducted which can further delay timeframes. If cell therapies manufactured under the new process have a worse safety or efficacy profile than the prior investigational product or the process is less reproducible than the previous process, we may need to re-evaluate the use of that manufacturing process, which could significantly delay or even result in the halting of our clinical trials.

We have product liability insurance and insurance to cover certain business interruption events. However, because our level of insurance is capped, it may be insufficient to fully compensate us if any of these events were to occur in the future.

***Our manufacturing process needs to comply with regulations, and any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.***

In order to commercially produce our products, we will need to comply with the FDA's and other regulatory authorities' cGMP requirements at our Navy Yard facility, vector facility and third party contract manufacturing facilities. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our third party contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements once the process has been approved. Any failure to follow cGMP or other regulatory requirements, reliably manufacture product or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our cell therapies as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our cell therapies, including leading to significant delays in the availability of our cell therapies for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing authorization applications for our cell therapies. Significant non-compliance could also result in the imposition of sanctions, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our cell therapies, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

Given we now manufacture cell therapies at our own U.S. manufacturing facility and lentiviral vectors at a dedicated U.K. vector facility, regulatory authorities might raise non-compliance issues or require us to make changes to the way in which we operate our facilities. This may result in a delay in our ability to manufacture cell therapies at our own facility or in our ability to supply vector material for use in the manufacturing process, including in connection with our collaboration with Galapagos. In addition, any cell therapy or vector produced in any of our facilities might not be able to meet regulatory requirements and we may be unable to recruit and maintain sufficient staff to enable manufacture of products within required timescales. Resourcing of cell manufacturing facilities is increasingly competitive, which may restrict the number of available skilled operators which can be recruited at our manufacturing facilities. Any failure to meet regulatory requirements or produce cell therapies and vector according to regulatory requirements could result in delays to our clinical programs, potential side effects and even fatalities to patients and may result in withdrawal of regulatory approval for our manufacturing facility.

As part of our BLA review process for lete-cel, our Navy Yard manufacturing facility will be inspected for compliance with regulatory requirements. Should the facility fail to pass such inspection and changes be required to the facility or manufacturing process, there will be a delay in the approval of marketing authorization for lete-cel.

***We have our own manufacturing capabilities which may result in increased costs being incurred by us.***

During 2017, we opened a manufacturing facility for our T-cell products within our Navy Yard facility in Philadelphia, Pennsylvania and have started manufacturing T-cells for use in our clinical trials. Regulatory authorities, in particular the FDA, might not continue to approve our ability to manufacture T-cells or other cell therapies at the Navy Yard facility.

Our ability to successfully manufacture our own cell therapies at our facilities within a reasonable period of time and within currently projected costs is dependent on a number of factors including:

- our ability to recruit the required employees at a suitable level and experience and within required timescales and to maintain employment of such required employees;
- our ability to obtain regulatory approval for the facility and for the manufacture of cell therapies at the facility and to satisfy regulatory authorities on an ongoing basis;
- our ability to manufacture cell therapies reliably and reproducibly and to timescales sufficient to support required patient administration;
- our ability to manufacture cell therapies in compliance with the applicable regulatory requirements, including requirements applicable in the U.S., U.K. and EU;
- our ability to develop internal quality controls and processes sufficient to enable manufacture and supply of cell therapies at our facilities;
- our ability to establish comparability with currently used manufacturing processes and for such comparability data to be accepted by the appropriate regulatory authorities; and
- our ability to be able to fund the ongoing development including equipment requirements necessary for successful manufacture of cell therapies at our facilities.

Any delay or failure in manufacture at our facility could result in delays to the supply of cell therapies for our clinical programs or for commercial supply. Should any of our third party manufacturers also cease to be able to or be unable to supply cell therapies at a time where our own manufacturing facility is unable to produce cell therapies for use in our clinical programs or is unable to produce cell therapies at the required level, then we will be unable to support such clinical programs until alternative manufacturing capability is secured.

***Our autologous cell therapy products are patient-specific and we need to ensure that the correct product is administered to the correct patient.***

Administration of cell therapies is patient-specific. The process requires careful handling of patient-specific products and fail-safe tracking to ensure that the tracking process is without error and that patient samples are tracked from patient removal, through manufacturing and re-administration to the same patient. While such mechanisms are in place, should the tracking process fail, whether at our own facility, a third party facility or at any point in the manufacturing and supply process, a patient could receive another patient's T-cells resulting in significant toxicity and potentially patient fatality. We will need to invest in enhanced systems, such as bar coding, to further ensure fail safe tracking. There is always a risk of a failure in any such system. Inability to develop or adopt an acceptable fail-safe tracking methodology and handling regime may delay or prevent us from receiving regulatory approval and/or result in significant toxicity and potentially patient fatality if a patient receives another patient's T-cells. This risk may be

increased where cell therapies are used in clinical programs that we do not control or sponsor and, should an error be made in the administration of our cell therapies in such clinical programs, this could affect the steps required in our own clinical programs and manufacturing process requiring the addition of further tracking mechanisms to ensure fail-safe tracking. The tracking systems required to further ensure safe patient administration may also require increased administration to satisfy other regulatory requirements, for example, data protection requirements in Europe. The need to ensure tracking systems are adequate and to comply with these additional regulatory requirements may result in delay to the start of trials or the need to obtain additional regulatory licenses or consents prior to starting such trials.

#### **Risks Related to Government Regulation**

##### ***Regulatory authorities may impose a hold on our clinical trials.***

A clinical trial may be suspended or terminated by us or a collaborator, IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a cell therapy, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we or our collaborators experience termination of, or delays in the completion of, any clinical trial of our cell therapies, the commercial prospects for our cell therapies will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

##### ***The FDA regulatory process can be difficult to predict, in particular whether for example, accelerated approval processes are available or further unanticipated clinical trials are required will depend on the data obtained in our ongoing clinical trials.***

The regulatory approval process and the amount of time it takes us to obtain regulatory approvals for our cell therapies will depend on the data that are obtained in our ongoing clinical trials and in one or more future registration or pivotal clinical trials. We may attempt to seek approval on a per indication basis for our cell therapies on the basis of a single pivotal trial or on the basis of data from a Phase 2 trial. While the FDA requires in most cases two adequate and well-controlled pivotal clinical trials to demonstrate the efficacy of a product candidate, a single trial with other confirmatory evidence may be sufficient where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically difficult. Depending on the data we obtain, the FDA or other regulatory authorities may require additional clinical trials to be carried out or further patients to be treated prior to the granting of any regulatory approval for marketing of our cell therapies. It is difficult for us to predict with such a novel technology exactly what will be required by the regulatory authorities in order to take our cell therapies to market or the timeframes under which the relevant regulatory approvals can be obtained.

##### ***Obtaining and maintaining regulatory approval of our cell therapies in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our cell therapies in other jurisdictions.***

Obtaining and maintaining regulatory approval of our cell therapies in one jurisdiction does not guarantee that we or our collaborators will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a cell therapy, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the cell therapy in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical programs or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a cell therapy must be approved for reimbursement before it can be approved for sale in

that jurisdiction. In some cases, the price that we or our collaborators intend to charge for our cell therapies is also subject to approval.

***We may be unable to obtain breakthrough or similar designations for our cell therapies or maintain the benefits associated with such designations.***

In 2012, the FDA established a Breakthrough Therapy designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases when “preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The designation of a cell therapy as a Breakthrough Therapy provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the cell therapy and ensure collection of appropriate data needed to support approval; more frequent written correspondence from the FDA about things such as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and Priority Review.

We have obtained RMAT designation (Regenerative Medicine Advanced Therapy designation) from the FDA for afami-cel for the treatment of synovial sarcoma. In January 2025, lete-cel was granted breakthrough therapy designation by the U.S. FDA for the treatment of patients with unresectable or metastatic myxoid liposarcoma who have received prior anthracycline-based chemotherapy, are positive for HLA-A\*02:01, HLA-A\*02:05, or HLA-A\*02:06, and whose tumor expresses the NY-ESO-1 antigen. We may apply for similar status or accelerated programs in other countries and for other of our products and indications. However, given the novel nature of our cell therapies, it is difficult for us to predict whether the FDA or other regulatory authorities will approve such requests or what further clinical or other data may be required to support an application for such accelerated approval procedures. It is possible that the FDA could rescind our RMAT or other designations, if the agency determines that our cell therapies no longer meet the qualifying criteria.

Breakthrough Therapy and RMAT designations do not change the standards for product approval, and products with such designations do not always obtain marketing approval or timely marketing approval. Additionally, other treatments from competing companies may obtain the designations and impact our ability to develop and commercialize our cell therapy, which may adversely impact our business, financial condition or results of operation.

We may also seek Accelerated Approval under the FDA’s Fast Track And Accelerated Approval programs, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For drugs and biologics granted Accelerated Approval such as afami-cel, post-marketing confirmatory trials have been required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence. Moreover, the FDA may withdraw approval of our cell therapy or indication approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our cell therapy fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug;
- other evidence demonstrates that our cell therapy is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post approval trial of our cell therapy with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant cell therapy.

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The FDA's Accelerated Approval program has come under increased scrutiny in recent years from both internal and external stakeholders have raised concerns that confirmatory trials have not been completed or have not demonstrated intended effect. Recent legislation (FDORA) has increased the FDA's authority to impose more stringent requirements on the timing and conduct of confirmatory trials, and on the FDA's ability to expedite the withdrawal from approval of a biological product when confirmatory trials have not been completed or do not show intended effect.

In Europe, the EMA has implemented the so-called Priority Medicines ("PRIME") scheme in order support the development and accelerate the approval of complex innovative medicinal products addressing an unmet medical need. The PRIME status enables early dialogue with the relevant EMA scientific committees and, possibly, some payers; and thus reinforces the EMA's scientific and regulatory support. It also opens accelerated assessment of the marketing authorization application (150 days instead of 210 days). The PRIME scheme, which is decided by the EMA, is reserved for medicinal products that may benefit from accelerated assessment, i.e. medicines of major interest from a public health perspective, in particular from a therapeutic innovation perspective.

In 2020, the EMA granted access to the PRIME scheme to afami-cel for the treatment of certain patients with synovial sarcoma. We may apply for PRIME status for other of our cell therapy products. There can be no assurance that any application will be successful in obtaining PRIME status.

***We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense as well as significant penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our cell therapies.***

Any regulatory approvals that we receive for our cell therapies will require surveillance to monitor the safety and efficacy of the cell therapy. The FDA may also require a REMS in order to approve our cell therapies, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Later discovery of previously unknown problems with our cell therapies, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on such products' manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- untitled or warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;

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- refusal to permit the import or export of our products;
- product seizure;
- injunctions;
- imposition of civil penalties; or
- criminal prosecution.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our cell therapies. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if following any pivotal clinical trial we were able to obtain accelerated approval of any of our cell therapies, for example afami-cel, the FDA will require us to conduct a confirmatory trial or trials to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory trial or trials may not support the clinical benefit, which would result in the approval being withdrawn.

***We may seek a conditional marketing authorization in Europe for some or all of our current cell therapies, but we may not be able to obtain or maintain such authorization.***

As part of its marketing authorization process, the EMA may grant marketing authorizations for certain categories of medicinal products on the basis of less complete data than is normally required, when doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use, or CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the centralized procedure (EMA's scientific assessment and European Commission's approval), including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the benefit/risk profile of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to

complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

Granting a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product are generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for one or more of our cell therapies, the CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied. This would delay the commercialization of our cell therapies as we would have to wait for a complete data package before submitting the marketing authorization application.

***We may not be able to obtain or maintain orphan drug exclusivity for our cell therapies.***

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages in-lieu of R&D tax credits and user-fee waivers.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing authorization application for the same drug for that time period. The applicable period is seven years in the U.S. and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA 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 addition, a competitor could avoid our orphan drug exclusivity, if its products is shown to be clinically superior. In Europe, the orphan exclusivity may be lost vis-à-vis another drug in cases the manufacturer is unable to assure sufficient quantity of the drug to meet patient needs or if that other product is proved to be clinically superior to the approved orphan product. Generally, the clinical superiority standards in the U.S. and in Europe are similar, and a product is clinically superior if it shows greater efficacy, greater safety, or makes a major contribution to patient care.

As a result of Brexit, as of January 1, 2021, incentives related to an orphan designation granted in the EU are limited to the EU and Ireland, but not Great Britain (England, Wales and Scotland). The competent authority in the U.K. (MHRA) will review applications for orphan designation at the time of a marketing authorization, and has announced that it will offer incentives in the form of market exclusivity and full or partial refunds for marketing authorization fees to encourage the development of medicines in rare diseases.

There can be no assurance that any of our cell therapies will be eligible for orphan drug designation in the U.S. or in other jurisdictions or that it will obtain orphan drug exclusivity upon approval or that we will not lose orphan drug designation for afami-cel and lete-cel. Inability to obtain orphan drug designation for a specific cell therapy or loss of such designation for afami-cel or lete-cel in the future would prevent any ability to take advantage of the financial benefits associated with orphan drug designation and would preclude us from obtaining marketing exclusivity upon approval, if any. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition.

The FDA's interpretation of the scope of orphan drug exclusivity has been the subject of recent litigation in the Eleventh Circuit Court of Appeals. In the *Catalyst* case, the appellate court concluded that the FDA has impermissibly narrowed the scope of orphan exclusivity to the approved indication or use, rather than the broader disease or condition which was the basis of the orphan drug designation. The FDA has announced that it will continue to follow its existing regulations, notwithstanding the court decision. However, it is possible that additional litigation may arise, and there is considerable uncertainty about the scope of any orphan drug exclusivity that our products may be awarded.

***Any failure by us to comply with existing regulations could harm our reputation and operating results.***

The production of cell therapies is highly regulated and subject to constant inspection. The regulatory environment may also change from time to time. Any failure to comply with regulatory requirements, whether in the U.S. or in other countries in which our cell therapies are supplied, may result in investigation by regulatory authorities, suspension of regulatory authorizations and, as a result, suspension of clinical programs or ability to supply any of our cell therapies and potentially significant fines or other penalties being imposed in relation to any breach. Any failure may also harm our reputation and impact our ability going forward to obtain regulatory approvals for other cell therapies or require us to undertake additional organizational changes to minimize the risk of further breach. A failure to comply may apply to any part of our business, for example, to the processes used for manufacture of our cell therapies (including the reliability of the process) or to the processes used for treatment of patients (including tracking of patient product and supply of patient-specific product).

***Our research and development activities utilize hazardous, radioactive and biological materials. Should such materials cause injury or be used other than in accordance with applicable laws and regulations, we may be liable for damages.***

We use hazardous and biological reagents and materials in our research and development at our U.K. site. We have obtained the appropriate certification or ensured that such certification has been obtained as required for the use of these reagents but our use is subject to compliance with applicable laws and there is a risk that should any third party or employee suffer injury or damage from radioactive, hazardous or biological reagents that we may incur liability or obligations to compensate such third parties or employees. We have employer's liability insurance and public liability insurance capped at certain limits; however, these amounts may be insufficient to compensate us if these events actually occur in the future.

***We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.***

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and our commercial partners may operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose actions, if non-compliant, could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U.K. and the U.S., and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

However, there is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-



corruption laws or Trade Control laws by U.K., U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

***If we are found in violation of federal or state “fraud and abuse” or other health care laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operations.***

If we obtain marketing approval for our products in the U.S., if at all, we will be subject to various federal and state health care “fraud and abuse” and other health care laws. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and use of pharmaceutical products that are granted marketing approval. Accordingly, arrangements with third-party payors, existing or potential customers and referral sources are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, and these laws and regulations may constrain the business or financial arrangements and relationships through which manufacturers market, sell and distribute the products for which they obtain marketing approval.

Such restrictions under applicable federal and state healthcare laws and regulations include the following the Anti-Kickback Statute, the Healthcare Reform Act, the False Claims Act, or FCA, federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Public reporting under the Physician Payments Sunshine Act, or Sunshine provisions, and other similar state laws, has resulted in increased scrutiny of the financial relationships between biopharmaceutical companies, teaching hospitals, physicians and other health care providers. Such scrutiny may negatively impact our ability to engage with physicians and other health care providers on matters of importance to us. In addition, government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports. If the data reflected in our reports are found to be in violation of any of the Sunshine provisions or any other U.S. federal, state or local laws or regulations that may apply, or if we otherwise fail to comply with the Sunshine provisions or similar requirements of state or local regulators, we may be subject to significant civil, and administrative penalties, damages or fines.

Violation of any of the laws described above or any other governmental laws and regulations may result in penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs and imprisonment. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products. Additionally, if we are found in violation of one or more of these laws our business, results of operations and financial condition may be adversely affected.

#### **Risks Related to Our Reliance Upon Third Parties**

***We rely on Galapagos in relation to the performance of the collaboration agreement between us and for progression of uza-cell into the clinic.***

Development of uza-cell will depend heavily on the performance of Galapagos under the ongoing collaboration and payments made by our collaborators to us in relation to such development. In particular:

- Research funding, development or sales milestones or product royalties or any other sums might not become due or payable to us at any time or on the time frames currently expected.
- Galapagos has a right to terminate the collaboration agreement. Termination may impact not only our requirement for additional investment or capital but also the timeframes within which current research and development programs (including clinical programs) can be performed or whether we can continue to perform those research and development programs at all.

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- Any research or development plan agreed upon in our collaborations may be delayed or may be unsuccessful or fail to result in therapies that are feasible for further development or commercialization.
- Changes to the development plans or agreement may impact the timing and extent of milestone payments, the amount of research funding received, the nature of the relationship with our collaborators or the scope of the collaboration.
- Delay in performance of responsibilities under any research or development plan could impact our ability to progress uza-cell through research and development, including where Galapagos delays the performance of any of its responsibilities.
- Galapagos has the ability to influence or control certain decisions relating to the development of therapies covered by collaboration. This ability could result in delays to the research and development programs covered by the collaboration or changes to the scope of those programs, including the disease indications relevant to such clinical programs.

***We rely on third parties to manufacture and supply our cell therapies and to develop next-generation cell therapies, and we may have to rely on third parties to produce and process our cell therapies, if approved.***

We rely on a limited number of third-party manufacturers and third party service providers for clinical trial product supplies and services and supply of vector for our commercial product, and as a result we are exposed to the following risks:

- We may be unable to contract with manufacturers on commercially acceptable terms or at all because the number of potential manufacturers is limited and the FDA, EMA and other comparable foreign regulators must approve any replacement manufacturer, which would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, and develop substantially equivalent processes for, production of our cell therapies after receipt of any applicable regulatory approval.
- We may not be able to obtain lentiviral delivery manufacturing slots with third party contract manufacturers within the timescales we require for supply of lentiviral delivery vector or to obtain agreed dates for such manufacturing slots sufficiently in advance of the requirement for supply.
- Our third-party manufacturers might be unable to timely formulate and manufacture our cell therapies or produce the quantity and quality required to meet our clinical trial and commercial needs or to provide commercially viable product on the timelines we require or at all, which may necessitate a change in third-party manufacturers or a requirement to further develop internal capabilities, all of which may result in delays to clinical trials or to commercialization plans.
- With any new manufacturing process or new CMO we will need to transfer the manufacturing process or new process to that CMO. Any delay in the development and transfer of these new processes to the third-party contract supplier or inability of the third-party contract supplier to replicate or carry out the transferred process at the appropriate level and quality or in a reproducible fashion will result in delays in our ability to progress clinical programs, further develop our cell therapies and obtain marketing approval for our cell therapies.
- Introduction of new raw material or intermediate material manufacturers, such as CMOs for vectors, may require comparability testing to be carried out to show that the manufacturing process and end material is comparable to the currently used manufacturing process and/or material. Any inability to show comparability or delay in comparability testing may result in delays to the supply of the affected materials and as a result delays to clinical trials.

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- Contract manufacturers may not be able to execute our manufacturing procedures appropriately, or we may be unable to transfer our manufacturing processes to contract manufacturers successfully or without additional time and cost. Even where CMOs fail to manufacture our cell therapies successfully, it may not be possible to achieve re-manufacture quickly or without expending resources or additional costs.
- Our future contract manufacturers may not perform as agreed, may be acquired by competitors or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our cell therapies. In addition, contract manufacturers may not manufacture within agreed timescales for manufacture and/or may cancel pre-agreed manufacturing slots, which would result in delays in manufacturing and could require us to find replacement manufacturers which may not be available to us on favorable terms or at all.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, EMA, and other comparable foreign regulators and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. Although we do not have day-to-day control over third-party manufacturers' compliance with these regulations and standards, we are responsible for ensuring compliance with such regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our cell therapies. Our third party manufacturers may use processes which infringe or potentially infringe third party intellectual property rights which may result in inability to use such processes going forward, an increase in the pricing of such processes or a need to change a different process.
- Our third party manufacturers may fail to perform testing and analysis services accurately, in a manner that can be interpreted or on a timely basis. This could delay or prevent release of our cell therapies and as a result delay clinical trials and patient treatment.
- Our third-party manufacturers could breach or terminate their agreement with us.
- Our third-party manufacturers may cease to be able to do business with us (whether for insolvency or other reasons, including takeover, merger or acquisition) at a time when we are unable to source such manufacture elsewhere or at our own manufacturing facility.
- Increased costs, unexpected delays, equipment failures, lack of reproducibility, labor shortages, natural disasters, power failures and numerous other factors which are outside of our control or which may be imposed by our CMOs. For example, moving to commercial phase manufacture usually incurs increased cost and qualification requirements at our CMOs. Such costs may be prohibitive, or such activities may not be able to be performed within appropriate timelines.
- Our collaborators or third party contract manufacturers may allocate their resources, materials, and services away from our cell therapy programs.

### ***Certain of the components required for manufacturing of our cell therapies come from sole source or limited source suppliers.***

Certain raw materials or precursor materials used in the manufacture and supply of our cell therapies may come from sole source or limited source suppliers. For example, there are currently a limited number of third party manufacturers within the U.S. that can supply us with our lentiviral delivery vector and ThermoFisher is currently the only supplier of the Dynabeads® CD3/CD28 technology. Should such suppliers be unable to supply or manufacture such raw materials or precursor materials either at all or within required timescales we may be unable to supply our cell therapies or such supply may be significantly delayed. Inability to obtain such raw materials or precursor materials may also necessitate changes in the manufacturing process used for supply of our cell therapies. Such changes to the

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manufacturing process may need to be developed internally or by a third party and may also require additional regulatory approvals to be obtained before they can be used for the manufacture and supply of our cell therapies for clinical trials.

In addition, we are focusing manufacture of our cell therapies and vectors for those cell therapies in a few manufacturing sites, namely our Navy Yard facility for certain autologous cell therapies and with a third party contract manufacturers for lete-cel. Should any facility be unable to manufacture our cell therapies or vectors for those cell therapies for any reason, including natural disaster, contamination or for any regulatory reason, we may be unable to supply cell therapies for our clinical trials unless we can procure manufacture from a third party manufacturer. There is no assurance that we will be able to procure manufacture from a third party manufacturer or that such manufacture will be provided within the timescales we require or at an acceptable price. Any change in manufacturer used to produce our cell therapies requires notification to regulatory authorities which can be time consuming. There is no assurance that regulatory authorities will agree that any change in manufacturer is acceptable or that the processes used at such manufacturer are comparable to the processes previously used and additional evidence of comparability may be required.

***We rely on third parties to conduct our clinical trials.***

We depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical programs and sponsored clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs and trial sites (either directly or through a third party consultant), which may result in delays to our development timelines and increased costs. We rely heavily on these third parties over the course of our clinical trials, and we do not have day-to-day control of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with applicable protocols and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for cell therapies in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations and guidelines, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing authorization applications. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties which could be limited, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical trials and preclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug or biologic development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of, or successfully commercialize our cell therapies. As a result, our financial results and the commercial prospects for our cell therapies would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our timelines for bringing our cell therapies to market, if at all.

## **Risks Related to Our Intellectual Property**

### ***We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.***

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. In so doing, we may place our intellectual property at risk of being invalidated, held unenforceable, narrowed in scope or otherwise limited. Further, an adverse result in any litigation or defense proceedings may increase the risk of non-issuance of pending applications. In addition, if any licensor fails to enforce or defend its intellectual property rights, this may adversely affect our ability to develop and commercialize our T-cells and to prevent competitors from making, using, and selling competing products. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence and/or outcome of any such litigation could harm our business, results of operations and financial condition.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary 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 securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs.

We may also be forced to defend our intellectual property rights in opposition proceedings in front of patent offices in order to obtain or continue to hold granted patent rights. Our inability to successfully defend our patents and patent applications in opposition proceedings may result in a reduction in the scope of protection offered by such patents or patent applications or alternatively the patents or patent applications may be revoked. Anonymous third party oppositions have been lodged against certain of our European patents. None of these oppositions relate to any cases which claim any of our clinical candidates.

### ***We may not be able to protect our proprietary technology in the marketplace or the cost of doing so may be prohibitive or excessive.***

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection (i.e., know-how), and confidentiality agreements to protect the intellectual property of our cell therapies. However, patent protection may not be available for some of the cell therapies or technology we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business results of operations and financial condition may be harmed.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Enforcement of patents may also be cost prohibitive and we may be unable to prevent competitors from entering the market with products that are similar to or the same as our cell therapies.

In addition, patents have a limited lifespan. In most countries, including the U.S., the standard expiration of a patent is 20 years from the effective filing date. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If patent term extension is not available, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and non-clinical data, and then may be able to launch their product earlier than might otherwise be the case.

### ***We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.***

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely, in

part, on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Proceedings to enforce trade secrets can be cost prohibitive and we may be unable to prevent our competitors using our trade secrets.

***If third parties claim that our activities or products infringe upon their intellectual property, our operations could be adversely affected.***

There is a substantial amount of litigation, both within and outside the U.S., involving patents and other intellectual property rights in the pharmaceutical industry. If we or our third party suppliers were found to infringe upon a patent or other intellectual property right, or if we failed to obtain or renew a license under a patent or other intellectual property right from a third party, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, we may be required to pay damages, including triple damages if the infringement is found to be willful, suspend the manufacture of certain of our cell therapies or reengineer or rebrand our cell therapies, if feasible, or we may be unable to enter certain new product markets. Any such claims could also be expensive and time-consuming to defend and divert management's attention and resources.

***Licenses may be required from third parties in relation to any of cell therapies developed or commercialized by us.***

We may identify third-party intellectual property rights that are required to enable the further development, commercialization, manufacture or development of our cell therapies or other cell therapies, including our allogeneic cell therapies. Licenses to such intellectual property rights may or may not be available on commercial terms that are acceptable to us. As a result we may incur additional license fees for such intellectual property rights, or the cost and expenses to identify an alternative route for commercialization, that does not require the relevant third-party intellectual property rights, or the cost and diversion of resources required to challenge any such third party intellectual property rights.

***Where we license certain technology from a third party, the prosecution, maintenance and defense of the patent rights licensed from such third party may be controlled by the third party which may impact the scope of patent protection which will be obtained or enforced.***

Where we license patent rights or technology from a third-party, control of such third party patent rights may vest in the licensor, particularly where the license is non-exclusive or field restricted. This may mean that we are not able to control or affect the scope of the claims of any relevant third-party patent or have control over any enforcement of such a patent. Where a licensor brings an enforcement action, this could negatively impact our business or result in additional restrictions being imposed on the license we have and the scope of such license or result in invalidation or limitation of the scope of the licensed patent. In addition, should we wish to enforce the relevant patent rights against a third person, we may be reliant on consent from the relevant licensor or the cooperation of the licensor. The licensor may refuse to bring such action and leave us unable to restrict competitor entry into the market.

***Issued patents protecting our T-cells or other cell therapies could be found invalid or unenforceable if challenged in court or at the USPTO.***

If we or one of our collaborators initiate legal proceedings against a third party to enforce a patent protecting one of our cell therapies, the defendant could counterclaim that the patent protecting our cell therapy, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our cell therapies.

## **Risk of Legal Proceedings**

### ***We are subject to legal proceedings, the outcome of which could be unfavorable to us***

We are involved in or may in the future become involved in disputes as well as legal proceedings. MD Anderson has recently served legal proceedings on Adaptimmune. Those proceedings are at a very early stage and have not been resolved. Regardless of merit, resolving these proceedings or any other legal proceedings brought against us, is expensive, time consuming and disruptive to our operations, including to its management.

The outcome of legal proceedings is inherently uncertain and it may not be possible to resolve such proceedings on terms favorable to us. The final outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against the Company that could materially affect our financial condition and operating results. MD Anderson are claiming damages of over \$21 million (excluding legal fees and costs of court) which if deemed payable will materially affect our financial condition.

## **General Business Risks**

### ***We depend upon our key personnel and our ability to attract and retain employees.***

We are heavily dependent on the ongoing employment and involvement of certain key employees in particular, Adrian Rawcliffe, our Chief Executive Officer; William Bertrand, our Chief Operating Officer; John Lunger, our Chief Patient Supply Officer; Dr. Joanna Brewer, our Chief Scientific Officer; Dr. Elliot Norry, our Chief Medical Officer; and Cintia Piccina, our Chief Commercial Officer. We do not hold key-man insurance for our senior managers.

Our business is dependent on our ability to recruit experienced and suitably trained employees or consultants, and to retain such employees on a long-term basis. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice which could result in us being unable to conduct our business in accordance with current timelines and priorities. Although we have employment agreements with all of our employees in the U.K., these employment agreements provide for a mutual nine months' notice period in the case of Dr. Brewer; mutual three months' or two months' notice periods in the case of senior managers and mutual one-month notice periods for all other employees. In the U.S., the employment agreements provide for at-will employment except that, under their employment agreements, Mr. Rawcliffe, Mr. Bertrand, Mr. Lunger, Dr. Norry and Ms. Piccina must provide 60 days' written notice and our senior vice-presidents must provide 30 days' written notice. This means that any of our employees in the U.S., except for Mr. Rawcliffe, Mr. Bertrand, Mr. Lunger, Dr. Norry, Ms. Piccina and our senior vice-presidents, could leave our employment at any time, with or without notice.

In November 2024, we announced that we were reducing our headcount by approximately 33% and targeting approximately \$300 million in aggregate cost savings over the next four years. The restructuring aims to prioritize the commercial sarcoma franchise and R&D programs with the highest potential return on invested capital and transformational benefit to patients, and the Company plans to focus an increasing proportion of its corporate functions in the US. As part of this restructuring, we announced in December 2024 that Helen Tayton-Martin, our Co-founder and Chief Business and Strategy Officer, and Gavin Wood, our Chief Financial Officer, would step down on March 31, 2025 and May 31, 2025 respectively. Any headcount reduction may impact our ability to retain other experienced members of staff which could in turn impact our ability to progress our development programs on the timelines currently expected.

### ***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, drug candidates or technologies. Any such transaction will result in an impact on resource requirements and expenditure and may pose significant integration challenges or disrupt our management or business. For example, these transactions may entail numerous operational and financial risks, including exposure to additional liabilities, incurrence of substantial debt or dilutive issuances or equity to pay for transactions,

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changes in our management, increases in our costs and expenses beyond those expected, difficulty in integrating the new company or assets and impacts to relationships with third parties.

***We expect to face intense competition, which may be from companies with greater resources and experience than we have.***

The pharmaceutical industry, and the immuno-oncology industry specifically, is highly competitive and subject to rapid developments in treatment options. Competitors include large global pharmaceutical companies, biotechnology companies, specialty immune-therapy companies and universities and research organizations, whether alone or in collaboration with other entities. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and may also be able to progress clinical candidates through clinical studies quicker than we are able to. Mergers and acquisitions within the pharmaceutical and biotechnology industry can also result in resources being concentrated within our competitors. Our competitors may also have better developed commercialization capabilities and already established sales forces and manufacturing capability.

Within in any particular cancer indication we may face competition from other cell therapy companies, from personalized medicine approaches, from other modalities of treatment, alternative drug products or therapies or from pre-existing treatment regimens used to treat patients with that cancer indication.



***Our internal information technology systems, or those of our partners, third-party CROs or other contractors or consultants, may fail or suffer cybersecurity incidents, including related to data protection and privacy laws and adversely affect our business and operations.***

In the ordinary course of business, we collect, store, use, transmit, disclose and otherwise process proprietary, confidential and sensitive data (including personal data such as health-related data), intellectual property and trade secrets. We may process such information on our internal networks or rely upon third-party service providers, partners, CROs and other contractor and consultants, and technologies, to operate critical business systems to process such information in a variety of contexts (including, without limitation, third-party providers of cloud-based infrastructure, personnel email and other functions). Despite the implementation of security policies and procedures, the computer systems on which such information is processed or stored may be subject to cybersecurity threats. Our third-party providers may also be subject to cybersecurity threats which they do not detect on a timely basis and which may in turn impact our business.

We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. In the event of a cybersecurity attack, breach loss or compromise of critical or sensitive information, including personal information, and could give rise to legal liability and regulatory action under data protection and privacy laws such as the General Data Protection Regulation (“GDPR”) and relevant member state law in the European Union, the California Consumer Privacy Act and the California Privacy Rights Act (“CCPA”), and other domestic state and federal privacy laws that have been or may be passed such as HIPAA, and such laws may result in liability through private actions and enforcement or could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate. Moreover, because we maintain sensitive company data on our computer networks, including our intellectual property and proprietary business information, any such security breach may compromise information stored on our networks and may result in significant data losses or theft of our intellectual property or proprietary business information. Our current cybersecurity liability insurance, and any such insurance that we may obtain in the future, may not cover the damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, our reputation could be harmed and we could incur significant liabilities and the further development, clinical evaluation, or commercialization of our product candidates could be disrupted.

***We are exposed to risks related to currency exchange rates.***

We conduct a significant portion of our operations within the U.K. in both U.S. dollars and pounds sterling and our arrangements with GSK are denominated in pounds sterling. Changes in currency exchange rates have had and could have a significant effect on our operating results. Exchange rate fluctuations between the U.S. dollar and local currencies create risk in several ways, including the following: weakening of the pound sterling may increase the cost of overseas research and development expenses and other costs outside the U.K.; strengthening of the U.S. dollar may decrease the value of any future revenues denominated in other currencies. Effects of exchange rates on transactions and cash deposits held in a currency other than the functional currency of a subsidiary can distort our financial results; and commercial pricing and profit margins are affected by currency fluctuations.

#### **Risks Related to Ownership of our American Depositary Shares (ADSs)**

***The market price and trading volume of our ADSs may be volatile.***

Many factors may have a material adverse effect on the market price of the ADSs, including but not limited to:

- the commencement, enrollment or results of our planned clinical trials;
- the loss of any of our key scientific or management personnel;

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- announcements of the failure to obtain regulatory approvals or receipt of a complete response letter from the FDA;
- announcements of undesirable restricted labeling indications or patient populations, or changes or delays in regulatory review processes;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to T-cells;
- any adverse changes to our relationship with licensors, manufacturers or suppliers;
- the failure of our testing and clinical trials;
- unanticipated safety concerns;
- the failure to retain our existing, or obtain new, collaboration partners;
- announcements concerning our competitors or the pharmaceutical industry in general;
- the achievement of expected product sales and profitability;
- the failure to obtain reimbursements for T-cells, if approved for marketing, or price reductions;
- manufacture, supply or distribution shortages;
- acquisitions or mergers and business deals announced by us or our competitors;
- the progress of competing treatment options and products or advent of new products which could impact the uptake or commercial value of our cell therapies;
- actual or anticipated fluctuations in our operating results;
- our cash position;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions;
- the trading volume of ADSs on the Nasdaq Global Select Market (“Nasdaq”);
- sales of our ADSs by us, our executive officers and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets including, but not limited to, as resulting from geopolitical factors and natural disasters and economic effects of such factors; and
- changes in accounting principles.

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In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause the price of our ADSs to decline rapidly and unexpectedly. In the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and could divert our management and other resources.

***We may not be able to maintain compliance with the continued listing requirements of Nasdaq.***

Our American Depository Shares (ADSs) are listed on Nasdaq. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price must not fall below \$1.00 per ADS for 30 consecutive business days. On November 1, 2024, we received a notice from The Nasdaq Stock Market (“Nasdaq”) that the Company is not in compliance with Nasdaq’s Listing Rule 5450(a)(1), because the minimum bid price of the Company’s American Depository Shares (“ADSs”) had been below \$1.00 per share for 30 consecutive business days (the “Notice”). The Notice has no immediate effect on the listing or trading of the Company’s ADSs on The Nasdaq Global Select Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has 180 calendar days, or until April 30, 2025, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company’s ADSs must be at least \$1.00 per ADS for a minimum of ten consecutive business days during this 180 calendar day grace period, unless Nasdaq exercises its discretion to extend this ten-day period. In the event the Company does not regain compliance with the minimum bid price requirement by April 30, 2025, the Company may be eligible for an additional 180 calendar day compliance period if it elects to transfer to The Nasdaq Capital Market. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement, and would need to provide written notice of its intention to cure the bid price deficiency during the second compliance period. However, if it appears to Nasdaq’s staff that the Company will not be able to cure the deficiency or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities would be subject to delisting. The Company may appeal any such determination to delist its securities, but there can be no assurance that any such appeal would be successful.

The Company intends to monitor the closing bid price of its ADSs and assess potential actions to regain compliance with Nasdaq’s Listing Rule 5450(a)(1). However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or that we will otherwise maintain compliance with other Nasdaq listing requirements. If we fail to regain and maintain compliance with the minimum bid price requirement or to meet the other applicable continued listing requirements in the future and Nasdaq decides to delist our ADSs, the delisting could adversely affect the market price and liquidity of our ADSs, reduce our ability to raise additional capital and result in operational challenges and damage to investor relations and market reputation.

***Substantial future sales of our ADSs in the public market, or the perception that these sales could occur, could cause the price of the ADSs to decline and dilute shareholders.***

Substantial future sales of our ADSs in the public market, or the perception that these sales could occur, could cause the market price of the ADSs to decline. Sales of a substantial number of our ADSs in the public market could occur at any time. In addition, we have registered an aggregate of 365,181,309 ordinary shares that we may issue under our equity compensation plans and, as a result, they can be freely sold in the public market upon issuance and following conversion into ADSs, but subject to volume limitations applicable to affiliates under Rule 144. Additionally, the majority of ordinary shares that may be issued under our equity compensation plans also remain subject to vesting in tranches over a four-year period. As of December 31, 2024, an aggregate of 129,110,391 options over our ordinary shares had vested and become exercisable. If a large number of our ADSs are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ADSs and impede our ability to raise capital in the future.

***We incur increased costs as a result of being a public company whose ADSs are publicly traded in the U.S. and our management must devote substantial time to public company compliance and other compliance requirements.***

As a U.S. public company whose ADSs trade on Nasdaq, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition and must comply with the Nasdaq listing requirements and other applicable securities rules and regulations. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq 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.

Complying with the rules and regulations applicable to public companies substantially increased our legal and financial compliance costs and made and continue to make some activities more time-consuming and costly. Our insurance costs have increased, particularly for directors and officers liability insurance, and we may be required to incur further substantial increased costs to maintain the same or similar coverage or be forced to accept reduced coverage in future. 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 increase our net loss and may require us to reduce costs in other areas of our business or increase the requirement for future financing. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs from Nasdaq, fines, sanctions and other regulatory action and potentially civil litigation

***Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidate.***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of shareholders. The incurrence of additional indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

***We may be classified as a passive foreign investment company in any taxable year and U.S. holders of our ADSs could be subject to adverse U.S. federal income tax consequences.***

The rules governing passive foreign investment companies, or PFICs, can have adverse effects for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. The determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. In addition, it is not entirely clear how to apply the income test to a company like us, which for any particular taxable year may have gross income that is either entirely passive or that significantly exceeds any active gross income, but the overall losses of which from research and development activities exceed the overall amount of its gross income for that year. Based on our estimated gross income, the average value of our assets, including goodwill and the nature of our active business, although not free from doubt, we do not believe that the Company was classified as a PFIC for U.S. federal income tax purposes for the U.S. taxable year ended December 31, 2024. There can be no assurance, however, that we will not be considered to be a PFIC for this taxable year or any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within our control, generally cannot be determined until the close of the taxable year in question and is determined annually.

If we are a PFIC, U.S. holders of our ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. A U.S. holder of our ADSs may be able to mitigate some of the adverse U.S. federal income tax consequences described above with respect to owning the ADSs if we are classified as a PFIC, provided that such U.S. investor is eligible to make, and validly makes, a “mark-to-market” election. In certain circumstances a U.S. Holder can make a “qualified electing fund” election to mitigate some of the adverse tax consequences described with respect to an ownership interest in a PFIC by including in income its share of the PFIC’s income on a current basis. However, we do not currently intend to prepare or provide the information that would enable a U.S. Holder to make a qualified electing fund election.

Investors should consult their own tax advisors regarding our PFIC status for any taxable year and the potential application of the PFIC rules to an investment in our ADSs or ordinary shares.

***If a United States person is treated as owning at least 10% of the value or voting power of our shares, such holder may be subject to adverse U.S. federal income tax consequences.***

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our shares, such U.S. holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” (“CFC”) in our group. As of the closing of the strategic business combination between Adaptimmune Therapeutics plc and TCR<sup>2</sup> Therapeutics Inc. on June 1, 2023, our group includes a directly held U.S. subsidiary that is 100% owned by Adaptimmune Therapeutics plc, resulting in a subsidiary CFC within our group.

A United States shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by CFCs, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with CFC reporting obligations may subject a United States shareholder to significant monetary penalties.

We cannot provide any assurance that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and taxpaying obligations applicable under the controlled foreign corporation rules of the Code. U.S. holders should consult their tax advisers regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

***If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management’s review of internal control over financial reporting.

Our compliance with applicable provisions of Section 404 requires that we incur substantial accounting expenses and expend significant management attention and time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. If we fail to staff our accounting and finance function adequately, if key employees within our accounting and finance function leave, or if we fail to maintain internal control over financial reporting adequate to meet the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed. Moreover, if we are not able to comply with the applicable requirements of Section 404 in a timely manner, we may be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Furthermore, if we are unable to conclude that our internal control over financial reporting is effective or if our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ADSs could decline, and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities. Failure to implement or maintain effective internal control systems

required of U.S. public companies could also restrict our access to the capital markets. The occurrence of any of the foregoing would also require additional financial and management resources.

***U.S. investors may have difficulty enforcing civil liabilities against our company, our directors, officers and members of senior management.***

We are incorporated under the laws of England and Wales. The rights of holders of our ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our articles of association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations organized in, for example, Delaware. Some of our directors, officers and members of senior management reside outside the U.S., and a substantial portion of our assets and all or a substantial portion of the assets of such persons are located outside the U.S. As a result, it may be difficult for you to serve legal process on us or our directors and executive officers or have any of them appear in a U.S. court. The U.S. and the U.K. do not currently have a treaty providing for the recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. The enforceability in the U.K. of any judgment of a U.S. federal or state court will depend on the particular facts of the case as well as the laws and any treaties in effect at the time, including conflicts of laws principles (such as those bearing on the question of whether a U.K. court would recognize the basis on which a U.S. court had purported to exercise jurisdiction over a defendant). In this context, there is doubt as to the enforceability in the U.K., in original actions or in actions for enforcement of judgments of U.S. courts, of civil liabilities based solely on the federal securities laws of the U.S.. In addition, awards for punitive damages in actions brought in the U.S. or elsewhere may be unenforceable in the U.K. An award for monetary damages under the U.S. securities laws would likely be considered punitive if it did not seek to compensate the claimant for loss or damage suffered and was intended to punish the defendant.

***Provisions in the U.K. City Code on Takeovers and Mergers that may have anti-takeover effects do not apply to us.***

The U.K. City Code on Takeovers and Mergers, or the Takeover Code, applies to an offer for, among other things, a public company whose registered office is in the U.K. if the company is considered by the Panel on Takeovers and Mergers, or the Takeover Panel, to have its place of central management and control in the United Kingdom (or the Channel Islands or the Isle of Man). This is known as the “residency test.” The test for central management and control under the Takeover Code is different from that used by the U.K. tax authorities. Under the Takeover Code, the Takeover Panel will determine whether we have our place of central management and control in the United Kingdom by looking at various factors, including the structure of our Board, the functions of the directors and where they are resident.

In July 2018, the Takeover Panel confirmed that, based on our current circumstances, we are not subject to the Takeover Code. As a result, our shareholders are not entitled to the benefit of certain takeover offer protections provided under the Takeover Code. We believe that this position is unlikely to change at any time in the near future but, in accordance with good practice, we will review the situation on a regular basis and consult with the Takeover Panel if there is any change in our circumstances which may have a bearing on whether the Takeover Panel would determine our place of central management and control to be in the United Kingdom.

**Item 1B. Unresolved Staff Comments**

None.

**Item 1C. Cybersecurity**

***Risk Management and Strategy***

We have processes in place to regularly assess, manage and identify potential risks from cybersecurity threats. Our cybersecurity policies and processes are integrated into our overall risk management program. To protect our information systems from cybersecurity threats, we use various security tools and processes that are designed to help identify and investigate any security incidents in a timely manner. When any risk or threat is identified we have a designated group of individuals including representatives from our information security team, finance team, compliance teams and legal teams who are involved in the assessment of the risk based on probability and potential impact to key business systems and processes. Risks that are considered to have a high impact to our business are incorporated into our

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enterprise risk management program. The tracking of these risks and the processes we have in place to address cybersecurity threats are tracked as part of our overall risk management program overseen by the Audit Committee of our board of directors.

We collaborate with third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes. These include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of cybersecurity risks, as well as to support associated mitigation plans when necessary.

As part of our overall risk management system, we train our staff on the safeguards we have in place to mitigate cybersecurity threats and ensure employees are able to identify potential attempts to breach our security and how to report and deal with any potential threats. We have procedures in place to assess and manage potential supply chain risks posed by third-party vendors and collaborators. As part of our cybersecurity risk management program, we work with certain third-party vendors to assess their cybersecurity processes, including a process for requesting that vendors who have access to our systems and data complete cybersecurity questionnaires prior to onboarding.

We have not identified any cybersecurity threats that have materially affected our ability to conduct our business or our financial standing. Refer to the risk factor captioned "*Our internal information technology systems, or those of our partners, third-party CROs or other contractors or consultants, may fail or suffer cybersecurity incidents, including related to data protection and privacy laws and adversely affect our business and operations*" in Part I, Item 1A. "Risk Factors" for additional description of cybersecurity risks and potential related impacts on our Company.

### **Governance**

Our board of directors oversees our risk management process, including as it pertains to cybersecurity risks. The Audit Committee of the board oversees our risk management program on behalf of the Board of Directors, which focuses on the most significant risks. Audit Committee meetings include discussions of any specific risk areas which are significantly increasing or which are of particular concern and at least once a year a third party expert in cybersecurity works with the Audit Committee and our Information Management team to assess the processes and controls we have in place around cybersecurity

We have introduced corporate policies and training on these policies for all of our staff. Our Information Management team, and in particular our information security team together with the corporate compliance team are responsible for ensuring compliance with these corporate policies. Our Chief Operating Officer and Compliance Officer oversees our policies and is primarily responsible to assess and manage material risks from cybersecurity threats, with assistance from third party experts as appropriate and our legal team. Our Global VP of Information Management has overall responsibility for our day to day cybersecurity procedures. We also have a Director heading up our global security and cybersecurity team and a dedicated member of the team overseeing cybersecurity threats and activities. Together those individuals have over 20 years of combined experience of information security.

### **Item 2. Properties**

The following table summarizes the facilities we lease as of December 31, 2024, including the location and size of the facilities, and their primary use.

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<u>Location</u>	<u>Approximate Square Feet</u>	<u>Primary Usage</u>	<u>Lease Expiration Dates</u>
Abingdon, Oxfordshire, United Kingdom	67,140	Corporate headquarters , Research, Development, Process Development, Manufacturing, Administration	October 2041
Abingdon, Oxfordshire, United Kingdom	46,017	Manufacturing, Process Development, Research	October 2041
Philadelphia, Pennsylvania, United States	47,700	Manufacturing, Process Development, Research	October 2031
Cambridge, Massachussetts, United States	22,890	Research, Development, Process Development	January 2026

As of December 31, 2024, all of the above sites were utilized by the Company.

We believe that our existing facilities are adequate for our near-term needs and will continue to keep our space requirements under review.

### **Item 3. Legal Proceedings**

On December 2, 2024, the University of Texas M.D. Anderson Cancer Center (“MD Anderson”) served litigation in the District Court of Harris County against Adaptimmune LLC (“Adaptimmune”). The litigation relates to a Strategic Alliance Agreement between MD Anderson and Adaptimmune dated September 23, 2016. MD Anderson claims damages of over \$21 million (excluding legal fees and costs of court) caused by Adaptimmune’s breach of contract. Alternatively, MD Anderson brings an action for quantum meruit, promissory estoppel, unjust enrichment, negligent misrepresentation and reformation. Adaptimmune provided its Original Answer, Affirmative Defenses, Special Exceptions and Counterclaims on January 22, 2025 denying all allegations of the MD Anderson petition and counterclaiming for breach of contract. MD Anderson filed a motion to dismiss Adaptimmune’s counterclaim, Special Exceptions and Original Answer to the counterclaim denying all allegations in the counterclaim on February 11, 2025. The case has not yet proceeded to discovery stage and we do not believe there is any merit to the claims being brought by MD Anderson.

Save as provided above, as of December 31, 2024, we were not a party to any material legal proceedings.

### **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**

#### **General Market Information**

Our ADSs have been listed on The Nasdaq Global Select Market since May 6, 2015 and are traded under the symbol “ADAP”. Each ADS represents six ordinary shares.

#### **Holders**

As of March 21, 2025, there were approximately 27 holders of record of our ordinary shares, par value £0.001 per share, and approximately 16 holders of record of our ADSs. The closing sale price per ADS on Nasdaq on December 31, 2024 was \$0.5387.



### Equity Compensation Plans

For information about our equity compensation plans, see Part III, Item 11, below

### Sales of Unregistered Securities

We did not sell any unregistered securities during the year ended December 31, 2024.

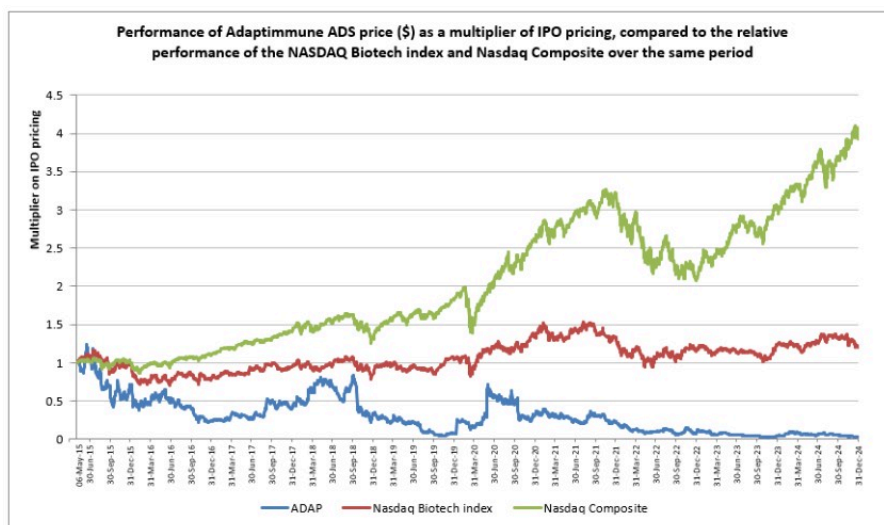
### Company Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2024.

### Stock Performance Graph

*Notwithstanding any statement to the contrary in any of our previous or future filings with the Securities and Exchange Commission, the following information relating to the price performance of our ADSs shall not be deemed “filed” with the Securities and Exchange Commission or “soliciting material” under the Exchange Act and shall not be incorporated by reference into any such filings.*

The following graph compares the cumulative total shareholder return on our ADSs with that of the Nasdaq Biotech Index and the Nasdaq Composite Index for the period that our ADSs were publicly traded, which commenced on May 6, 2015. We selected the Nasdaq Biotech Index because our ADSs trade on The Nasdaq Global Select Market and we believe this indicates our relative performance against a group consisting of more similarly situated companies.



**Item 6. [Reserved]**

### 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 in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report. In addition to our historical consolidated financial information, the following discussion contains*

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*forward-looking statements that reflect our plans, estimates, beliefs and expectations. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in Part I, Item 1A. "Risk Factors."*

## **Overview**

We are a commercial-stage biopharmaceutical company working to redefine the treatment of solid tumor cancers with cell therapies. With the approval by the U.S. Food and Drug Administration ("FDA") of our first biologics license application ("BLA") for TECELRA, which is the first engineered T-cell therapy for the treatment of a solid tumor cancer approved in the U.S., we are now focused on its launch and commercialization.

We are planning commercial launch for our second T-cell immunotherapy, lete-cel, for people with synovial sarcoma and myxoid liposarcoma in 2026. This product will significantly expand our treatable patient population within our commercial sarcoma franchise with up to \$400 million annual peak combined US sales from TECELRA and lete-cel. We estimate that approximately 400 newly diagnosed patients per year are biomarker eligible for TECELRA, and an incremental 600 newly diagnosed synovial sarcoma and myxoid liposarcoma patients per year in the US will be biomarker eligible for lete-cel.

In addition to our commercial sarcoma franchise we remain committed to our collaboration with Galapagos which uses our uza-cel candidate manufactured using the Galapagos manufacturing process. A clinical trial authorization to start a Phase 1 trial in head and neck cancer is planned for 2025.

During the fourth quarter of 2024 we announced that we were ceasing further investment in all non-core programs. We are undertaking a reduction in headcount of approximately 29% and a reduction of total operating expenses of approximately 25% (as compared to 2024 operating expenses). As of the end of February 2025, the majority of the headcount reduction has been completed. As part of this restructuring in December 2024, we also announced changes to our executive leadership team. In addition, we are implementing additional cost reduction for our preclinical PRAME and CD70 programs and are evaluating all strategic options to maximize shareholder value.

### ***TECELRA and Commercialization***

We are focused on the commercialization of TECELRA for the treatment of advanced synovial sarcoma and for which we received FDA approval on August 1, 2024. As of March 18, 2025, 20 ATCs are available to initiate the treatment journey for our patients and ten patients have been apheresed. We are confident that our full network of approximately 30 ATCs will be active by the end of 2025, covering an estimated 80% of patients treated in sarcoma centers of excellence. Companion diagnostics for biomarker detection are approved and available and we have adequate manufacturing capacity to meet orders. AdaptimmuneAssist is available to support our patients and HCPs.

### ***Letetresgene autoleucel ("lete-cel")***

Lete-cel targets the NY-ESO antigen and has been in clinical trials (the IGNUYTE-ESO trial) for people with synovial sarcoma and myxoid round cell liposarcoma (myxoid liposarcoma). It is the second product in our sarcoma franchise. Final data for the IGNUYTE-ESO trial were reported at the Connective Tissue Oncology Society Annual Meeting ("CTOS") in November 2024.

In January 2025, lete-cel was granted breakthrough therapy designation by the U.S. FDA for the treatment of patients with unresectable or metastatic myxoid liposarcoma who have received prior anthracycline-based chemotherapy, are positive for HLA-A\*02:01, HLA-A\*02:05, or HLA-A\*02:06, and whose tumor expresses the NY-ESO-1 antigen.

### ***Clinical Programs***

During 2025 we anticipate filing an IND for ADP-5701 for a Phase 1 trial in Head and Neck Cancer in collaboration with Galapagos. The trial will utilize the uza-cel engineered T-cell Receptor (TCR) and Galapagos' innovative decentralized cell therapy manufacturing platform. Uza-cel has shown encouraging results in head and neck cancer with partial responses in four out of five patients to date in a Phase 1 trial using Adaptimmune's manufacturing platform.

### ***Pre-Clinical Programs***

Our preclinical pipeline is focused on the development of T-cell therapies directed to PRAME (ADP-600) and CD70 (ADP-520). We have implemented additional cost saving measures in relation to these programs.

### ***Collaborations***

We entered into a clinical collaboration agreement with Galapagos in May 2024. Under the collaboration agreement we will conduct a clinical proof-of-concept trial to evaluate the safety and efficacy of uza-cel produced on Galapagos' decentralized manufacturing platform (ADP-5701) in patients with head and neck cancer.

Prior collaborations with Genentech, relating to the research of "off-the-shelf" cell therapies, and GSK, relating to the transition of the NY-ESO and PRAME programs, have now either terminated or been concluded.

### ***Corporate***

We have facilities in the U.S. in Philadelphia and Boston, and in the U.K.

During the fourth quarter of 2024 we announced that we were ceasing further investment in all non-core programs. We are undertaking a reduction in headcount of approximately 29% and a reduction of total operating expenses of approximately 25% (as compared to 2024 operating expenses). As of the end of February 2025, the majority of the headcount reduction has been completed. The restructuring aims to prioritize the commercial sarcoma franchise and R&D programs with the highest potential return on invested capital and transformational benefit to patients. As part of this restructuring the Company plans to focus an increasing proportion of its corporate functions in the US. We are also seeking strategic alternatives for our off-the shelf allogeneic cell therapy program. As part of this restructuring, we announced in December 2024 that Helen Tayton-Martin, our Co-founder and Chief Business and Strategy Officer, and Gavin Wood, our Chief Financial Officer, would step down on March 31, 2025 and May 31, 2025 respectively.

In addition to the restructuring announced in 2024, in March 2025 we announced implementation of additional cost reduction for the PRAME and CD70 programs. We are currently evaluating all strategic options for the Company and its programs.

On March 24, 2025 we entered into an amendment to the Loan Agreement. Under the amendment we will pre-pay \$25 million of the loan amount under the Loan Agreement together with certain accrued interest up to the date of such pre-payment.

### **Financial Operations Overview**

We have generated losses since our inception in 2008, during which time we have devoted substantially all of our resources to the research and development of our cell therapies. We expect to continue to incur losses for the foreseeable future and our net losses may fluctuate significantly from quarter to quarter. Even though we have obtained marketing approval for our first cell therapies, TECELRA, it will take a period of time before any significant revenue is realized and the amount of revenue is heavily dependent on the success of our commercialization and the costs of supplies including any post-marketing requirements we are subject to. Our expenses may fluctuate significantly

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depending on the progress of our clinical trials, requirements to conduct additional clinical trials (including as a result of the filing of a BLA), requirement for further manufacturing to support our development activities, investment in additional manufacturing capabilities, requirements to support collaborations or engagement with third parties and investment in resources and infrastructure to support the commercialization of our cell therapies. Further information can be found in Item 1A. Risk Factors.

**Revenue**

The Company generates product revenue from sales of TECELRA.

The Company generates development revenue from collaboration agreements with customers. The Company had three development revenue-generating contracts with customers in the years ended December 31, 2024 and 2023, respectively: a collaboration agreement with Astellas that was terminated as of March 6, 2023, the Galapagos Collaboration Agreement (from May 30, 2024), a strategic collaboration and license agreement with Genentech that was terminated as of September 23, 2024 and the GSK Termination and Transfer Agreement from April 11, 2023. The original collaboration and license agreement with GSK was terminated in 2022.

*The Genentech Collaboration and License Agreement*

On September 3, 2021, Adaptimmune Limited, a wholly owned subsidiary of Adaptimmune Therapeutics plc, entered into a Strategic Collaboration and License Agreement with Genentech, Inc. (“Genentech”) and F. Hoffman-La Roche Ltd. The collaboration has two components:

- 1) development of allogeneic T-cell therapies for up to five shared cancer targets
- 2) development of personalized allogeneic T-cell therapies utilizing  $\alpha\beta$  T-cell receptors (TCRs) isolated from a patient, with such therapies being administered to the same patient.

The parties would collaborate to perform a research program, initially during an eight-year period (which may be extended for up to two additional two-year terms at Genentech’s election upon payment of an extension fee for each two-year term), to develop the cell therapies, following which Genentech would determine whether to further develop and commercialize such therapies. The Company received an upfront payment of \$150 million in October 2021 and milestone payments of \$20 million and \$15 million in December 2022 and 2023, respectively.

The Company identified the following performance obligations under the Genentech Collaboration Agreement: (i) research services and rights granted under the licenses for each of the initial “off-the-shelf” collaboration targets, (ii) research services and rights granted under the licenses for the personalized therapies, (iii) material rights relating to the option to designate additional “off-the-shelf” collaboration targets and (iv) material rights relating to the two options to extend the research term. The revenue allocated to the initial “off-the-shelf” collaboration targets and the personalized therapies was recognized as development progressed. The revenue allocated to the material rights to designate additional “off-the-shelf” collaboration targets would have been recognized from the point that the options were exercised and then as development progressed, in line with the initial “off-the-shelf” collaboration targets, or at the point in time that the rights expired. The revenue from the material rights to extend the research term would have been recognized from the point that the options were exercised and then over the period of the extension, or at the point in time that the options expired.

On April 12, 2024, we announced the termination of the Genentech Collaboration Agreement. The termination was accounted for as a contract modification on a cumulative catch-up basis. The termination did not change the nature the performance obligations identified but resulted in a reduction of the transaction price as the additional payments and variable consideration that would have been due in periods after October 7, 2024 will now never be received. The termination resulted in a cumulative catch-up adjustment to revenue recognized at the date of the termination of \$101.3 million.

On September 23, 2024, Adaptimmune Limited entered into a Mutual Release Agreement with Genentech. The Mutual Release Agreement, among other things, resolved and released each party from any and all past, present and

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future disputes, claims, demands and causes of action, whether known or unknown, related to the Genentech Collaboration Agreement in any way. Under the terms of the Mutual Release Agreement, Genentech will pay \$12.5 million which was received in October 2024, upon which the Genentech Collaboration Agreement was terminated. The Mutual Release Agreement was effective immediately as of September 23, 2024. The Mutual Release Agreement resulted in all remaining performance obligations being fully satisfied and the remaining deferred revenue and the additional payment were both recognized as total revenue of \$37.8 million in the third quarter of 2024.

### *The GlaxoSmithKline (“GSK”) Collaboration and License Agreement*

The GSK Collaboration and License Agreement consisted of multiple performance obligations. GSK nominated its third target under the Collaboration and License Agreement in 2019, and the Company received \$3.2 million following the nomination of the target and a further \$4.2 million in June 2021 following achievement of a development milestone, which were being recognized as revenue as development progressed.

The collaboration was terminated in October 2022. A further amendment to the collaboration agreement was entered into on December 19, 2022 for the deletion of certain provisions relating to GSK’s post termination manufacturing and supply obligations and payment of £5.0 million (\$6.0 million) by GSK to Adaptimmune which was received in the first quarter of 2023. The revenue associated with this payment and the remaining deferred income relating to the third target of \$0.4 million were recognized as revenue in the year-ended December 31, 2022.

### *The GSK Termination and Transfer Agreement*

On April 11, 2023, the Company announced the entry of the Company and GSK into a Termination and Transfer regarding the return to the Company of rights and materials comprised within the PRAME and NY-ESO cell therapy programs. The parties will work collaboratively to ensure continuity for patients in ongoing lete-cel clinical trials forming part of the NY-ESO cell therapy program.

As part of the Termination and Transfer Agreement, sponsorship of the ongoing IGNYTE and LTFU trials relating to the NY-ESO cell therapy program will transfer to the Company. In return for this, the Company received an upfront payment of £7.5 million in June 2023 following the execution of the Termination and Transfer Agreement and further milestone payments of £3 million, £12 million, £6 million and £1.5 million to the Company in September and December 2023 and June and August 2024, respectively. No further payments are due from GSK under the Termination and Transfer Agreement.

The Company has identified the following performance obligations under the Termination and Transfer Agreement: (i) to take over sponsorship and complete the IGNYTE trial and (ii) to take over sponsorship and complete the LTFU trial. The revenue allocated to both obligations is recognized over time from the point that sponsorship of the active trials that make up the trial transfer, based on the number of patients transferred and still actively enrolled to date on the trial at a given period-end relative to the total estimated periods of active patient enrollment over the estimated duration of the trial.

### *The Astellas Collaboration Agreement*

In January 2020, the Company entered into a collaboration agreement with Astellas. The Company received \$50.0 million as an upfront payment after entering into the agreement. Under the agreement the parties would agree on up to three targets and would co-develop T-cell therapies directed to those targets pursuant to an agreed research plan. For each target, Astellas would fund co-development up until completion of a Phase 1 trial for products directed to such target. In addition, Astellas was also granted the right to develop, independently of Adaptimmune, allogeneic T-cell therapy candidates directed to two targets selected by Astellas. Astellas would have sole rights to develop and commercialize products resulting from these two targets.

The agreement consisted of the following performance obligations: (i) research services and rights granted under the co-exclusive license for each of the three co-development targets and (ii) the rights granted for each of the two independent Astellas targets. The revenue allocated to the co-development targets was recognized as the development of

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products directed to the targets progressed up until completion of a Phase 1 trial. The revenue allocated to each of the research licenses for the targets being independently developed by Astellas was to be recognized when the associated license commenced, which was upon designation of a target by Astellas.

The Company and Universal Cells mutually agreed to terminate the Astellas Collaboration Agreement as of March 6, 2023 (the “Termination Date”). In connection with the termination, all licenses and sublicenses granted to either party pursuant to the Collaboration Agreement ceased as of the Termination Date. There were no termination penalties in connection with the termination, however the Company was still entitled to receive reimbursement for research and development work performed up to and including a period of 30 days after the Termination Date.

The termination was accounted for as a contract modification and the modification resulted in the remaining unsatisfied and partially satisfied performance obligations under the collaboration becoming fully satisfied. The aggregate transaction price of the contract modification was \$42.4 million, which was primarily comprised of deferred income relating to the third co-development target and the two independent targets and was recognized in full in March 2023.

### *The Galapagos Collaboration and Exclusive License Agreement*

On May 30, 2024, the Company entered into the Galapagos Collaboration Agreement. The Galapagos Collaboration Agreement includes an option for Galapagos to exclusively license the TCR T-cell therapy candidate uza-cel, manufactured on Galapagos’s decentralized manufacturing platform, in head and neck cancer and potential future solid tumor indications. Under the Galapagos Collaboration Agreement, we will conduct a clinical proof-of-concept trial to evaluate the safety and efficacy of uza-cel produced on Galapagos’ decentralized manufacturing platform in patients with head and neck cancer.

The Company will receive initial payments of \$100 million, comprising \$70 million upfront and \$30 million of research and development funding, option exercise fees of up to \$100 million (the amount depending on the number of indications in relation to which the option is exercised), additional development and sales milestone payments of up to a maximum of \$465 million, plus tiered royalties on net sales. The \$70 million upfront payment and \$15 million of upfront research and development funding was received in June 2024.

The Company has identified a performance obligation relating to the various activities required to complete the POC trial and a material right associated with the exclusive license option. The Company expects to satisfy the POC Trial obligation over time over the period that the trial is completed, based on an estimate of the percentage of completion of the trial determined based on the costs incurred on the trial as a percentage of the total expected costs. The revenue allocated to the material right associated with the exclusive license option will be recognized from the point that the option is either exercised and control of the license has passed to Galapagos or the option lapses.

### ***Cost of Goods Sold***

Cost of goods sold represents the costs involved in the manufacture of our commercial products including raw materials, internal manufacturing and staff costs including a share of overheads and other costs incurred in bringing inventories to their existing condition and location prior to sale. Cost of goods sold also includes the costs for excess or obsolete inventory.

### ***Research and Development Expenses***

Research and development expenditures are expensed as incurred. Research and development expenses consist principally of the following:

- salaries for research and development staff and related expenses, including benefits;
- costs for production of preclinical compounds and drug substances by contract manufacturers;

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- fees and other costs paid to contract research organizations in connection with additional preclinical testing and the performance of clinical trials;
- costs associated with the development of a process to manufacture and supply our lentiviral vector and cell therapies for use in clinical trials;
- costs to develop manufacturing capability at our U.S. facility for manufacture of cell therapies for use in clinical trials;
- costs relating to facilities, materials and equipment used in research and development;
- costs of acquired or in-licensed research and development which does not have alternative future use;
- costs of developing assays and diagnostics;
- an allocation of indirect costs clearly related to research and development;
- amortization and depreciation of property, plant and equipment and intangible assets used to develop our cells therapies; and
- share-based compensation expenses.

These expenses are partially offset by:

- reimbursable tax and expenditure credits from the U.K. government.

Research and development expenditure is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government. As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime for small and medium sized companies (“SME R&D Tax Credit Scheme”), whereby our principal research subsidiary company, Adaptimmune Limited, is able to surrender the trading losses that arise from its research and development activities for a payable tax credit of up to approximately 33.4% of eligible research and development expenditures before April 1, 2023, decreasing to 18.6% after April 1, 2023. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects for which we do not receive income. Subcontracted research expenditures are eligible for a cash rebate of up to approximately 21.7% before April 1, 2023, decreasing to 12.1% after April 1, 2023. A large proportion of costs in relation to our pipeline research, clinical trials management and manufacturing development activities, all of which are being carried out by Adaptimmune Limited, are eligible for inclusion within these tax credit cash rebate claims.

Expenditures incurred in conjunction with our collaboration agreements are not qualifying expenditures under the SME R&D Tax Credit Scheme but certain of these expenditures can be reimbursed through the U.K. research and development expenditure credit scheme (the “RDEC Scheme”). Under the RDEC Scheme tax relief is given at 20% of allowable R&D costs, which may result in a payable tax credit at an effective rate of approximately 15% of qualifying expenditure for the year ended December 31, 2024.

On July 18, 2023, the U.K. Government released draft legislation on proposed changes to the U.K. research and development regimes which was subsequently enacted on February 22, 2024. These changes include combining the current SME R&D Tax Credit Scheme and RDEC Schemes with a single 20% gross rate applying to all claims with an exception for R&D Intensive SMEs. For entities which qualify as R&D Intensive SMEs, a higher effective cash tax

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benefit of 27% will be available. The legislation also includes changes to other rules and types of qualifying expenditure, such as the treatment of subcontracted and overseas costs.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, which depends upon the timing of initiation of clinical trials and the rate of enrollment of patients in clinical trials. The duration, costs, and timing of clinical trials and development of our cell therapies will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical trials and other research and development activities;
- uncertainties in clinical trial enrollment rates;
- future clinical trial results;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals; and
- supply and manufacture of lentiviral vector and cell therapies for clinical trials.

A change in the outcome of any of these variables may significantly change the costs and timing associated with the development of that cell therapy. For example, if the FDA, or another regulatory authority, requires us to conduct clinical trials beyond those that we currently anticipate will be required for regulatory approval, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

***Selling, General and Administrative expenses***

Our selling, general and administrative expenses consist principally of:

- salaries for employees other than research and development staff, including benefits;
- provisions for restructuring activity;
- business development expenses, including travel expenses;
- professional fees for auditors, lawyers and other consulting expenses, including those incurred in relation to the merger with TCR<sup>2</sup>;
- costs of facilities, communication, and office expenses;
- cost of establishing commercial operations;
- information technology expenses;
- amortization and depreciation of property, plant and equipment and intangible assets not related to research and development activities; and
- share-based compensation expenses.



### ***Other Income (Expense), Net***

Other income (expense), net primarily comprises foreign exchange gains (losses). We are exposed to foreign exchange rate risk because we currently operate facilities in the United Kingdom and United States. Our expenses are generally denominated in the currency in which our operations are located, which are the United Kingdom and United States. However, our U.K.-based subsidiary incurs significant research and development costs in U.S. dollars and, to a lesser extent, Euros. Our U.K. subsidiary has an intercompany loan balance in U.S. dollars payable to the ultimate parent company, Adaptimmune Therapeutics plc. Since July 1, 2019, the intercompany loan has been considered as being a long-term investment as repayment is not planned or anticipated in the foreseeable future. It is Adaptimmune Therapeutics plc's intent not to request payment of the intercompany loan for the foreseeable future. The foreign exchange gains or losses arising on the revaluation of intercompany loans of a long-term investment nature are reported within other comprehensive (loss) income, net of tax.

Our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. We seek to minimize this exposure by maintaining currency cash balances at levels appropriate to meet forthcoming expenditure in U.S. dollars and pounds sterling. To date, we have not used hedging contracts to manage exchange rate exposure, although we may do so in the future.

In addition to currency fluctuations, adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs, changes to fiscal and monetary policy, tighter credit, and higher interest rates, could materially adversely affect the Company by, for example, driving higher input costs and/or impacting the Company's ability to raise future financing.

### ***Taxation***

We are subject to corporate taxation in the United Kingdom and the United States. We incur tax losses and tax credit carryforwards in the United Kingdom. No net deferred tax assets are recognized on our U.K. losses and tax credit carryforwards because there is currently no indication that we will make sufficient taxable profits to utilize these tax losses and tax credit carryforwards. On June 10, 2021, the U.K. 2021 Finance Bill was enacted. Under this bill, the rate of U.K. corporation tax increased to 25% from April 1, 2023, with lower rates and tapered relief applied to companies with profits below £250,000.

We benefit from reimbursable tax credits in the United Kingdom through the SME R&D Tax Credit Scheme as well as the RDEC Scheme which are presented as a deduction to research and development expenditure.

Our subsidiary in the United States, Adaptimmune LLC, has generated taxable profits due to a Service Agreement between our U.S. and U.K. operating subsidiaries and is subject to U.S. federal corporate income tax of 21%. Due to its activity in the United States, and the sourcing of its revenue, Adaptimmune LLC is not currently subject to significant state or local income taxes due to being located in a Keystone Opportunity Zone, which eliminates our state and local taxes in Pennsylvania. No net deferred tax assets are recognized on our U.S. deferred tax attributes, which includes capitalized research and development expenditure and share-based payment temporary differences, because there is not sufficient objectively verifiable evidence that we will make sufficient taxable profits to utilize these attributes. The Company also benefits from the U.S. Research Tax Credit and Orphan Drug Credit.

TCR<sup>2</sup> Therapeutics, Inc. ("TCR<sup>2</sup>") has incurred net losses since acquisition. TCR<sup>2</sup>'s operating loss and tax credit carryforwards and other tax attributes are reduced by a valuation allowance to the amount supported by reversing taxable temporary differences because there is currently no indication that we will make sufficient taxable profits to utilize these deferred tax assets. The utilization of TCR<sup>2</sup>'s losses is also subject to limitations under Section 382 of the Internal Revenue Code, due to the change in ownership.

In the future, if we generate taxable income in the United Kingdom, we may benefit from the United Kingdom's "patent box" regime, which would allow certain profits attributable to revenues from patented products to be taxed at a rate of 10%. As we have many different patents covering our products, future upfront fees, milestone fees, product revenues, and royalties may be taxed at this favorably low tax rate.

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U.K. Value Added Tax (“VAT”) is charged on all qualifying goods and services by VAT-registered businesses. An amount of 20% of the value of the goods or services is added to all relevant sales invoices and is payable to the U.K. tax authorities. Similarly, VAT paid on purchase invoices paid by Adaptimmune Limited and Adaptimmune Therapeutics plc is reclaimable from the U.K. tax authorities.

**Results of Operations**

**Comparison of Years Ended December 31, 2024 and 2023**

The following table summarizes the results of our operations for the years ended December 31, 2024, and 2023, together with the changes to those items (in thousands):

	Year ended December 31,		Increase/decrease	
	2024	2023		
Product revenue, net	\$ 1,236	\$ —	\$ 1,236	—%
Development revenue	176,796	60,281	116,515	193%
<b>Revenue</b>	<b>\$ 178,032</b>	<b>\$ 60,281</b>	<b>\$ 117,751</b>	<b>195%</b>
Cost of goods sold	(70)	—	(70)	100%
Research and development expenses	(149,060)	(126,509)	(22,551)	18%
Selling, general and administrative expenses	(87,261)	(73,513)	(13,748)	19%
Impairment of long-lived assets	(10,401)	—	(10,401)	—%
<b>Total operating expenses</b>	<b>(246,792)</b>	<b>(200,022)</b>	<b>(46,770)</b>	<b>23%</b>
<b>Operating loss</b>	<b>(68,760)</b>	<b>(139,741)</b>	<b>70,981</b>	<b>(51)%</b>
Interest income	6,596	5,964	632	11%
Interest expense	(3,348)	—	(3,348)	—%
Gain on bargain purchase	—	22,049	(22,049)	(100)%
Other (expense) income, net	(1,726)	(807)	(919)	114%
<b>Loss before income tax expense</b>	<b>(67,238)</b>	<b>(112,535)</b>	<b>45,297</b>	<b>(40)%</b>
Income tax expense	(3,576)	(1,336)	(2,240)	168%
<b>Loss for the period</b>	<b>\$ (70,814)</b>	<b>\$ (113,871)</b>	<b>\$ 43,057</b>	<b>(38)%</b>

**Revenue**

Total revenue increased by \$117.8 million to \$178.0 million in the year ended December 31, 2024, compared to \$60.3 million for the year ended December 31, 2023, primarily due to the termination of the Genentech Collaboration Agreement in April 2024, resulting in a cumulative catch-up adjustment of \$101.3 million in the second quarter of 2024, and the subsequent Mutual Release Agreement, resulting in the remaining deferred revenue and additional payment being recognized as \$37.8 million of revenue in the third quarter of 2024. This compares to the termination of the Astellas Collaboration Agreement in the first quarter of 2023, which resulted in the remaining deferred revenue for the collaboration of \$42.4 million being recognized as revenue in March 2023.

Total revenue from Galapagos, Genentech and GSK in the year ended December 31, 2024 was \$0.5 million, \$163.9 million and \$12.3 million respectively, compared to \$44.0 million, \$15.8 million and \$0.5 million from Astellas, Genentech and GSK in 2023, respectively. The revenue recognized in 2024 and 2023 for Genentech and Astellas, respectively, includes the impact of the events noted above, as well as revenue recognized as research and development work for the collaborations was performed.

**Research and development expenses**

Research and development expenses increased by \$22.6 million to \$149.1 million for the year ended December 31, 2024 from \$126.5 million for the year ended December 31, 2023. Our research and development expenses comprise the following (in thousands):

	Year ended December 31,		Increase/decrease	
	2024	2023		
Salaries, materials, equipment, depreciation of property, plant and equipment and other employee-related costs <sup>(1)</sup>	\$ 95,483	85,492	\$ 9,991	11.7 %
Subcontracted expenditure	52,061	48,416	3,645	7.5 %
Manufacturing facility expenditure	9,184	6,922	2,262	32.7 %
Share-based compensation expense	3,875	3,061	814	26.6 %
In-process research and development costs	52	(1,840)	1,892	(102.8)%
Reimbursements receivable for research and development tax and expenditure credits	(11,467)	(15,542)	4,075	(26.2)%
Other	(128)	—	(128)	— %
	<u>\$ 149,060</u>	<u>\$ 126,509</u>	<u>\$ 22,551</u>	<u>17.8 %</u>

(1) These costs are not analyzed by project since employees may be engaged in multiple projects at a time.

The net increase in our research and development expenses of \$22.6 million for the year ended December 31, 2024, compared to the year ended December 31, 2023 was primarily due to the following:

- an increase of \$10.0 million in salaries, materials, equipment, depreciation of property, plant and equipment and other employee-related costs, which is driven primarily by an increase in the average number of employees engaged in research and development following the acquisition of TCR<sup>2</sup> in June 2023 and annual salary increases, and increased costs relating to property due to additional lease properties acquired following the acquisition of TCR<sup>2</sup>;
- an increase of \$3.6 million in subcontracted expenditures, including clinical trial expenses, contract research organization (CRO) costs and contract manufacturing expenses, largely driven by an increase in manufacturing work relating to our lete-cel product;
- an increase of \$2.3 million in manufacturing facility expenditure due to the consumption of batches of clinical materials that had not previously been impaired, compared to 2023 where clinical materials consumed were primarily those that had been impaired to nil in previous years and therefore no corresponding expense was recognized;
- an increase of \$1.9 million in in-process research and development costs due to a credit of \$1.9 million in 2023 that was not repeated in 2024; and
- a decrease in offsetting reimbursements receivable for research and development tax and expenditure credits of \$4.1 million due to decreases in the associated research and development costs for which the credits may be claimed and a reduction in the effective rate at which the tax credits can be claimed which was effective from April 1, 2023.

Our subcontracted costs for the year ended December 31, 2024 were \$52.1 million, compared to \$48.4 million in the same period of 2023. This includes \$39.8 million directly associated with our afami-cel, lete-cel and uza-cel T-cells and \$12.3 million of other costs.

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Our research and development expenses are highly dependent on the phases and progression of our research projects and will fluctuate depending on the outcome of ongoing clinical trials.

***Selling, general and administrative expenses***

Selling, general and administrative expenses increased by \$13.7 million to \$87.3 million for the year ended December 31, 2024 compared to \$73.5 million in the same period in 2023. Our selling, general and administrative expenses comprise the following (in thousands):

	Year ended December 31,		Increase/decrease	
	2024	2023		
Salaries, depreciation of property, plant and equipment and other employee-related costs	\$ 40,631	\$ 37,838	\$ 2,793	7 %
Restructuring charges	5,950	1,703	4,247	249 %
Other corporate costs	35,798	27,738	8,060	29 %
Share-based compensation expense	8,176	8,712	(536)	(6)%
Selling expenses	506	—	506	— %
Reimbursements	(3,800)	(2,478)	(1,322)	53 %
	<u>\$ 87,261</u>	<u>\$ 73,513</u>	<u>\$ 13,748</u>	<u>19 %</u>

The net increase in our selling, general and administrative expenses of \$13.7 million for the year ended December 31, 2024 compared to the same period in 2023 was largely due to:

- an increase of \$2.8 million in salaries, depreciation of property, plant and equipment and other employee-related costs compared to the equivalent period in 2023, due primarily increase in headcount as a result of the commercialization of TECELRA;
- an increase of \$4.2 million in restructuring charges due to the new restructuring program initiated in November 2024. The charge in 2023 relates to the restructuring program initiated in the fourth quarter of 2022 which was a smaller overall program and the majority of costs associated with that program were recognized in 2023; and
- an increase of \$8.1 million in other corporate costs due to an increase in accounting, legal and professional fees, due primarily to a combination of fees relating to business development work and fees relating to preparation for commercialization.

***Impairment of long-lived assets classified as held and used***

Impairment of long-lived assets classified as held and used relate to an impairment loss on leasehold improvement assets relating to the UK manufacturing facility, recognized following the restructuring and reprioritization of activities announced in November 2024.

***Interest income***

Interest income primarily relates to interest on cash, cash equivalents and available-for-sale debt securities and is presented net of amortization/accretion of the premium/discount on purchase of the debt securities. Interest income was \$6.6 million for the year ended December 31, 2024, compared to \$6.0 million for the year ended December 31, 2023.

***Interest expense***

Interest expense primarily relates to interest arising on the loan with Hercules Capital.

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**Other (expense) income, net**

Other (expense) income, net was an expense of \$1.7 million for the year ended December 31, 2024 compared to \$0.8 million for the year ended December 31, 2023. Other income, net primarily relates to unrealized foreign exchange gains and losses on cash and cash equivalents, and intercompany loans held in U.S. dollars by our U.K. subsidiary other than those of a long-term investment nature, where repayment is not planned or anticipated in the foreseeable future.

**Gain on Bargain Purchase**

The gain on bargain purchase of \$22.0 million arose in June 2023 from the strategic combination with TCR<sup>2</sup> Therapeutics Inc on June 1, 2023.

**Income taxes**

Income tax expenses were \$3.6 million for the year ended December 31, 2024 compared to \$1.3 million for the year ended December 31, 2023. Income taxes arise in the United States due to Adaptimmune LLC generating taxable profits. Income taxes have increased by \$2.2 million for the year ended December 31, 2024 compared to the same period in 2023 due to increased activity in our U.S. subsidiary resulting in higher intercompany recharges and higher taxable profit. We incur losses in the United Kingdom.

**Comparison of Years Ended December 31, 2023 and 2022**

The following table summarizes the results of our operations for the years ended December 31, 2023, and 2022, together with the changes to those items (in thousands):

	Year ended December 31,		Increase/decrease	
	2023	2022		
<b>Revenue</b>	<b>\$ 60,281</b>	<b>\$ 27,148</b>	<b>\$ 33,133</b>	<b>122 %</b>
Research and development expenses	(126,509)	(127,726)	1,217	(1)%
General and administrative expenses	(73,513)	(63,387)	(10,126)	16 %
<b>Total operating expenses</b>	<b>(200,022)</b>	<b>(191,113)</b>	<b>(8,909)</b>	<b>5 %</b>
<b>Operating loss</b>	<b>(139,741)</b>	<b>(163,965)</b>	<b>24,224</b>	<b>(15)%</b>
Interest income	5,964	1,542	4,422	287 %
Gain on bargain purchase	22,049	—	22,049	— %
Other (expense) income, net	(807)	(536)	(271)	51 %
<b>Loss before income tax expense</b>	<b>(112,535)</b>	<b>(162,959)</b>	<b>50,424</b>	<b>(31)%</b>
Income tax expense	(1,336)	(2,497)	1,161	(46)%
<b>Loss for the period</b>	<b>\$ (113,871)</b>	<b>\$ (165,456)</b>	<b>\$ 51,585</b>	<b>(31)%</b>

**Revenue**

Revenue increased by \$33.1 million to \$60.3 million in the year ended December 31, 2023, compared to \$27.1 million for the year ended December 31, 2022, primarily due to the termination of the Astellas collaboration, resulting in the remaining deferred income for the collaboration being recognized as revenue in March 2023.

**Research and development expenses**

Research and development expenses decreased by \$1.2 million to \$126.5 million for the year ended December 31, 2023 from \$127.7 million for the year ended December 31, 2022. Our research and development expenses comprise the following (in thousands):

	Year ended December 31,		Increase/decrease	
	2023	2022		
Salaries, materials, equipment, depreciation of property, plant and equipment and other employee-related costs <sup>(1)</sup>	\$ 85,492	86,611	\$ (1,119)	(1)%
Subcontracted expenditure	48,416	54,689	(6,273)	(11)%
Manufacturing facility expenditure	6,922	8,072	(1,150)	(14)%
Share-based compensation expense	3,061	6,264	(3,203)	(51)%
In-process research and development costs	(1,840)	2,316	(4,156)	(179)%
Reimbursements receivable for research and development tax and expenditure credits	(15,542)	(30,226)	14,684	(49)%
	<u>\$ 126,509</u>	<u>\$ 127,726</u>	<u>\$ (1,217)</u>	<u>(1)%</u>

(1) These costs are not analyzed by project since employees may be engaged in multiple projects at a time.

The net decrease in our research and development expenses of \$1.2 million for the year ended December 31, 2023, compared to the year ended December 31, 2022 was primarily due to the following:

- a decrease of \$1.1 million in salaries, materials, equipment, depreciation of property, plant and equipment and other employee-related costs, which is mainly driven by a decrease in the average number of employees engaged in research and development, offset partially by an increase in facility and other direct cost allocations, including those incurred following the acquisition of TCR<sup>2</sup>;
- a decrease of \$6.3 million in subcontracted expenditures, including clinical trial expenses, contract research organization (CRO) costs and contract manufacturing expenses, largely driven by a decrease in manufacturing costs including external lentiviral vector manufacturing;
- a decrease of \$3.2 million in share-based compensation expense due to a combination of lower fair value of options granted in 2023 compared to 2022 and due to high forfeiture credits due to redundancies in the same period; and
- a decrease of \$4.2 million in in-process research and development costs due to a credit of \$1.9 million relating to the release of a milestone that was previously accrued that is no longer expected to be paid, with no other in-process research and development costs recognized in 2023; offset by

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- a decrease in reimbursements receivable for research and development tax and expenditure credits of \$14.7 million due to decreases in the associated research and development costs for which the credits may be claimed and a reduction in the effective rate at which the tax credits can be claimed which was effective from April 1, 2023.

Our subcontracted costs for the year ended December 31, 2023 were \$48.4 million, compared to \$54.7 million in the same period of 2022. This includes \$26.4 million directly associated with our afami-cel and ADP-A2M4CD8 T-cells and \$22.0 million of other costs.

Our research and development expenses are highly dependent on the phases and progression of our research projects and will fluctuate depending on the outcome of ongoing clinical trials.

**General and administrative expenses**

General and administrative expenses increased by \$10.1 million to \$73.5 million for the year ended December 31, 2023 compared to \$63.4 million in the same period in 2022. Our general and administrative expenses comprise the following (in thousands):

	Year ended December 31,		Increase/decrease	
	2023	2022		
Salaries, depreciation of property, plant and equipment and other employee-related costs	\$ 37,838	\$ 31,903	\$ 5,935	19 %
Restructuring charges	1,703	2,297	(594)	(26)%
Other corporate costs	27,738	19,555	8,183	42 %
Share-based compensation expense	8,712	11,976	(3,264)	(27)%
Reimbursements	(2,478)	(2,344)	(134)	6 %
	<u>\$ 73,513</u>	<u>\$ 63,387</u>	<u>\$ 10,126</u>	<u>16 %</u>

The net increase in our general and administrative expenses of \$10.1 million for the year ended December 31, 2023 compared to the same period in 2022 was largely due to:

- an increase of \$5.9 million in salaries, depreciation of property, plant and equipment and other employee-related costs compared to the equivalent period in 2022, due primarily to severance and other related costs for former TCR<sup>2</sup> leadership and employees and an increase in depreciation following the completion of the construction of manufacturing facilities in the U.K. and U.S. The depreciation was allocated to general and administrative expenses based on the utilization of U.K. office in 2023 and, for the U.S. facility, the fact that the commercial operations for which the facility was constructed have not yet commenced;
- an increase of \$8.2 million in other corporate costs due primarily to an increase in accounting, legal and professional fees incurred in relation to entering into the TCR<sup>2</sup> Therapeutics Inc. merger agreement; offset by
- a decrease in share-based compensation expense of \$3.3 million due to a combination of lower fair value of options granted in 2023 compared to 2022 and due to high forfeiture credits due to

redundancies in the same period.

***Interest income***

Interest income primarily relates to interest on cash, cash equivalents and available-for-sale debt securities and is presented net of amortization/accretion of the premium/discount on purchase of the debt securities. Interest income was \$6.0 million for the year ended December 31, 2023, compared to \$1.5 million for the year ended December 31, 2022. The increase was primarily due to having net accretion of the discount on marketable securities for 2023; accretion on available-for-sale debt securities for the year ended December 31, 2023, was \$2.0 million compared to amortization of \$2.5 million for the year ended December 31, 2022. This was driven by a change in the Company's portfolio mix and through the acquisition of securities as part of the TCR<sup>2</sup> acquisition, where more securities were U.S. Treasury securities purchased at a discount rather than corporate debt securities purchased at a premium.

***Other (expense) income, net***

Other (expense) income, net was an expense of \$0.8 million for the year ended December 31, 2023 compared to \$0.5 million for the year ended December 31, 2022. Other income, net primarily relates to unrealized foreign exchange gains and losses on cash and cash equivalents, and intercompany loans held in U.S. dollars by our U.K. subsidiary other than those of a long-term investment nature, where repayment is not planned or anticipated in the foreseeable future.

***Gain on Bargain Purchase***

The gain on bargain purchase of \$22.0 million arose in June 2023 from the strategic combination with TCR<sup>2</sup> Therapeutics Inc on June 1, 2023.

***Income taxes***

Income tax expenses were \$1.3 million for the year ended December 31, 2023 compared to \$2.5 million for the year ended December 31, 2022. Income taxes arise in the United States due to Adaptimmune LLC generating taxable profits. Income taxes have decreased by \$1.2 million for the year ended December 31, 2023 compared to the same period in 2022 due to U.S. taxation regime changes coming into effect in 2022, affecting the period over which certain expenses may be deducted from taxable income. The impact of these changes was reduced in 2023 due to the effect of previously capitalized expenses in 2022 becoming deductible in 2023. We incur losses in the United Kingdom.

**Liquidity and Capital Resources**

***Sources of Funds***

Since our inception, we have incurred significant net losses and negative cash flows from operations. We financed our operations primarily through sales of equity securities, cash receipts under our Astellas Collaboration Agreement, Galapagos, Genentech and GSK Collaboration and License Agreements and GSK Termination and Transfer Agreement, government grants and research and development tax and expenditure credits. From inception through to December 31, 2024, we have raised:

- \$900.2 million of proceeds from issues of equity, net of issue costs;
- \$49.5 million, net of discount, drawn from the Hercules Capital loan facility;
- \$545.8 million through collaborative arrangements with Galapagos, Genentech, GSK and Astellas;
- \$154.9 million in the form of U.K. research and development tax credits and receipts from the U.K. RDEC Scheme; and



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- \$45.3 million in cash and cash equivalents and restricted cash and \$39.5 million of marketable securities were also acquired as part of the strategic combination with TCR<sup>2</sup> Therapeutics Inc.

We use a non-GAAP measure, Total Liquidity, which is defined as the total of cash and cash equivalents and marketable securities, to evaluate the funds available to us in the near-term. A description of Total Liquidity and reconciliation to cash and cash equivalents, the most directly comparable U.S. GAAP measure, are provided below under “Non-GAAP measures”.

As of December 31, 2024, we had cash and cash equivalents of \$91.1 million and Total Liquidity of \$151.6 million.

During the year ended December 31, 2024, the Company incurred a net loss of \$70.8 million, used cash of \$73.2 million in its operating activities, and generated revenues of \$178.0 million. The Company has incurred net losses since inception, and it expects to incur operating losses in foreseeable future periods.

The Company needs to acquire additional funding to finance its operating activities. We are actively looking at a variety of strategic opportunities and have engaged TD Cowen to evaluate strategic options for the Company and all of its programs. These could include potential mergers with third parties, acquisitions of part or all of the business together with other collaborations or partnerships. We are also considering acquiring additional funding through use of the Company ATM and/or other methods of raising equity financing. In addition the Company is also reducing its operating costs and has taken the decision to pause spending on its PRAME and CD70 programs. Although we are currently progressing plans to acquire additional funding, we may be unable to obtain sufficient additional capital to continue funding our operations or at all.

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. Management concluded that substantial doubt exists as to whether we can continue as a going concern within one year after the date the financial statements are issued. See Note 2(c) to the Consolidated Financial Statements for further detail.

None of the potential mitigating actions above are under the direct control of the Company. As a result, the substantial doubt over the Company’s ability to continue as a going concern within 12 months from the date of filing of this Annual Report on Form 10-K is not alleviated as of the date of filing.

**Cash Flows**

The following table summarizes the results of our cash flows for the years ended December 31, 2024, 2023 and 2022 (in thousands).

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Net cash used in operating activities	\$ (73,206)	\$ (140,880)	\$ (141,769)
Net cash (used in)/provided by investing activities	(58,952)	176,538	89,137
Net cash provided by financing activities	78,749	880	12,867
Cash, cash equivalents and restricted cash	93,206	147,017	109,602

*Year ended December 31, 2024 compared to year ended December 31, 2023*

Net cash used in operating activities decreased by \$67.7 million to \$73.2 million for the year ended December 31, 2024, compared to \$140.9 million for the year ended December 31, 2023. The net cash used in operating activities in the year end December 31, 2024, decreased as a result of the payments of \$85 million, \$13.8 million and \$9.7 million from Galapagos, Genentech and GSK, respectively, compared to \$16.8 million and \$34.7 million from

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Genentech and GSK in 2023, respectively, and receipts of R&D tax credits of \$44.3 million in 2024 compared to \$1.6 million in 2023. This was offset by an increase in operating expenditure as the Company commenced commercialization of TECELRA.

In addition, the U.K. R&D tax credits received in the year ended December 31, 2024, were \$42.7 million higher than that received during the year ended December 31, 2023, due to the U.K. R&D tax credit for the year ended December 31, 2022 being received in January 2024.

*Year ended December 31, 2023 compared to year ended December 31, 2022*

Net cash used in operating activities decreased by \$0.9 million to \$140.9 million for the year ended December 31, 2023, compared to \$141.8 million for the year ended December 31, 2022. The net cash used in operating activities in the year end December 31, 2023 decreased due to a decrease in operating expenditure as a result of the restructuring and de-prioritization of non-core programs that was initiated in the final quarter of 2022, which included a reduction in headcount of approximately 25% and de-prioritization of non-core activities and payments of \$16.8 million and \$34.7 million from Genentech and GSK in 2023, respectively as compared to payments of \$21.3 million from Genentech in 2022. This was partially offset following the business combination with TCR<sup>2</sup> which resulted in an increase in headcount of 39 and additional operating expenditures relating to activities originating from TCR<sup>2</sup> as well as various legal and professional fees relating to the acquisition. The impact of these changes resulted in a total combined increase of other corporate costs of \$8.2 million but a decrease in salaries, temporary staff, travel, training and other employee-related costs of \$2.2 million and subcontracted expenditure of \$6.3 million compared to the equivalent period in 2022.

In addition, the U.K. R&D tax credits received in the year ended December 31, 2023, were \$25.2 million lower than that received during the year ended December 31, 2022, because the U.K. R&D tax credit for the year ended December 31, 2022, which in previous years has been received in the fourth quarter of the year, was not received until January 2024.

*Components of cash flows from operating activities*

Net cash used in operating activities of \$73.2 million for the year ended December 31, 2024 comprised a net loss of \$70.8 million offset by noncash items of \$34.6 million and a net cash outflow of \$37.0 million from changes in operating assets and liabilities. The most significant items impacting the change in operating assets and liabilities include the \$85 million payments from Galapagos and \$33.2 million reduction in Research and development credits receivable. The noncash items consisted primarily of depreciation expense on plant and equipment of \$10.8 million, amortization of intangibles of \$0.4 million, impairment of long-lived assets of \$10.4 million, share-based compensation expense of \$12.1 million, accretion of marketable securities of \$1.3 million, unrealized foreign exchange losses of \$2.0 million and other losses of \$0.2 million.

Net cash used in operating activities of \$140.9 million for the year ended December 31, 2023 comprised a net loss of \$113.9 million offset by noncash items of \$2.1 million and a net cash outflow of \$25.0 million from changes in operating assets and liabilities. The most significant items impacting the change in operating assets and liabilities include the \$15 million additional payment from Genentech and \$34.7 million in payments from GSK, offset by a \$15.9 million increase in R&D tax credits receivable. The noncash items consisted primarily of depreciation expense on plant and equipment of \$9.5 million, amortization of intangibles of \$0.4 million, share-based compensation expense of \$11.8 million, accretion of marketable securities of \$2.0 million, unrealized foreign exchange losses of \$0.2 million and other losses of \$0.2 million.

Net cash used in operating activities of \$141.8 million for the year ended December 31, 2022 comprised a net loss of \$165.5 million offset by noncash items of \$25.2 million and \$1.5 million of unfavorable changes in operating assets and liabilities. The most significant items impacting the change in operating assets and liabilities include the \$20 million additional payment from Genentech and \$26.9 million in U.K. R&D tax credit receipts, offset by \$6 million receivable due from GSK. The noncash items consisted primarily of depreciation expense on plant and equipment of

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\$5.3 million, amortization of intangibles of \$0.8 million, share-based compensation expense of \$18.2 million, amortization of marketable securities of \$2.5 million, unrealized foreign exchange gains of \$2.4 million and other losses of \$0.8 million.

*Investing Activities*

Net cash used in investing activities was \$59.0 million for the year ended December 31, 2024 compared to net cash provided by investing activities of \$176.5 million for the year ended December 31, 2023. The net cash provided by investing activities for the respective periods consisted primarily of:

- purchases of property, plant and equipment of \$0.9 million and \$4.7 million in 2024 and 2023, respectively. Purchases of property, plant and equipment were higher in 2023 compared to 2024 as a result of expansion of our manufacturing facilities which was largely completed in 2022 and finalized in 2023;
- the acquisition of intangible assets of \$1.8 million and \$0.2 million in 2024 and 2023, respectively. Purchases of intangibles increased in 2024 due to commercialization-related software and technology acquired; and
- cash outflows from investment in marketable securities of \$100.4 million and \$76.0 million in 2024 and 2023, respectively; offset by
- cash inflows from maturity or redemption of marketable securities of \$44.1 million and \$211.0 million in 2024 and 2023, respectively.

The Company invests surplus cash and cash equivalents in marketable securities. Cash provided by investing activities decreased in the year ended December 31, 2024 due to a combination of the cash received from the TCR<sup>2</sup> acquisition in 2023 and a decrease in maturity or redemption of marketable securities due to 2023 having a high volume of investments maturing due to a combination of higher opening investments on January 1, 2023 compared to January 1, 2024 and the maturity of investments acquired as part of the TCR<sup>2</sup> acquisition, all of which matured in 2023.

Net cash provided by investing activities increased in the year ended December 31, 2023 due to cash received from the TCR<sup>2</sup> acquisition and an increase in maturity or redemption of marketable securities due to a combination of most securities on hand at December 31, 2022 reaching maturity in 2023 and from the maturity of investments acquired as part of the TCR<sup>2</sup> acquisition, all of which matured in 2023.

Net cash provided by investing activities was \$89.1 million for the year ended December 31, 2022 compared to net cash provided by investing activities of \$75.8 million for the year ended December 31, 2021. The Company invests surplus cash and cash equivalents in marketable securities. Cash provided by investing activities increased in the year ended December 31, 2022. Maturity or redemption of marketable securities of \$167.0 million was offset by investment in marketable securities of \$48.1 million in the year ended December 31, 2022.

*Financing Activities*

Net cash provided by financing activities was \$78.7 million, \$0.9 million and \$12.9 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Net cash provided by financing activities for the year ended December 31, 2024 consisted of net proceeds from public offerings of \$29.2 million, proceeds from exercise of share options of \$0.1 million and \$49.5 million proceeds from the issuance of borrowings, net of discount.

Net cash provided by financing activities for the year ended December 31, 2023 consisted of net proceeds from public offerings of \$0.6 million and proceeds from exercise of share options of \$0.3 million.

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Net cash provided by financing activities for the year ended December 31, 2022 consisted of net proceeds from public offerings of \$12.8 million and proceeds from exercise of share options of \$0.1 million.

**Non-GAAP Measures**

***Total Liquidity (a non-GAAP financial measure)***

Total Liquidity (a non-GAAP financial measure) is the total of cash and cash equivalents and marketable securities. Each of these components appears in the Consolidated Balance Sheet. The U.S. GAAP financial measure most directly comparable to Total Liquidity is cash and cash equivalents as reported in the consolidated financial statements, which reconciles to Total Liquidity as follows (in thousands):

	December 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 91,139	\$ 143,991
Marketable securities - available-for-sale debt securities	60,466	2,947
<b>Total Liquidity</b>	<b>\$ 151,605</b>	<b>\$ 146,938</b>

We believe that the presentation of Total Liquidity provides useful information to investors because management reviews Total Liquidity as part of its management of overall solvency and liquidity, financial flexibility, capital position and leverage. The definition of Total Liquidity includes marketable securities, which are highly liquid and available to use in our current operations.

**Material Cash Requirements**

As of December 31, 2024 the Company has not generated material revenue from product supplies or royalties. The Company's material cash requirements primarily relate to costs associated with the clinical development of our cell therapies, the development and enhancement of our manufacturing capabilities and securing a commercially viable manufacturing platform for all of our cell therapies, advancing additional cell therapies into preclinical testing and progressing such cell therapies through to clinical trials, supporting commercialization for TECELRA and to fund working capital, including for other general corporate purposes.

*Operating leases*

As of December 31, 2024 the Company had material operating lease obligations of \$24.0 million under non-cancellable leases for laboratory and office property in Oxfordshire, United Kingdom, Philadelphia, United States and Massachusetts, United States. Further details of our operating leases are provided in Item 2 and in Note 8 of Item 16 of this Annual Report.

*Purchase obligations*

As of December 31, 2024, the Company's unconditional purchase obligations for capital expenditure totaled \$1.5 million and are primarily composed of future payments for intangible assets including software licenses, of which the Company expects to incur \$0.9 million within one year and \$0.6 million within one to three years.

The Company also had non-cancellable commitments for the purchase of clinical materials, contract manufacturing, commercial activities and maintenance which have been committed but not yet paid up to \$16.6 million, of which the Company expects to incur \$11.2 million within one year, \$3.8 million within one to three years and \$1.6 million within three to five years. The amount and timing of these payments vary depending on the rate of progress of development.

Future payments associated with clinical trials are not considered purchase commitments because they are contingent on enrollment in clinical trials and the activities required to be performed by the clinical sites.

*MD Anderson*

In 2016, Adaptimmune entered into a multi-year strategic alliance with MD Anderson designed to expedite the development of T-cell therapies for multiple types of cancer. We and MD Anderson collaborated on a number of studies including clinical and preclinical development of our T-cell therapies. Under the terms of the agreement, we committed at least \$19.6 million to fund studies. The Company made an upfront payment of \$3.4 million to MD Anderson in the year ended December 31, 2017 and milestone payments of \$2.3 million, \$3.5 million, \$0.5 million and \$2.3 million in the years ended December 31, 2018, 2020, 2021 and 2022, respectively.

The collaboration ended on March 23, 2022, and enrolment has ceased, therefore the remaining clinical milestones totaling \$4.1 million will not be met or become payable by the Company. The remaining preclinical work can continue until completion; the Company expects that the remaining billing upon completion less amounts invoiced to date totals approximately \$0.5 million.

On 2 December 2024, MD Anderson served litigation in the District Court of Harris County against Adaptimmune LLC (“Adaptimmune”) relating to the strategic alliance. MD Anderson claims damages of over \$21 million (excluding legal fees and costs of court) caused by Adaptimmune’s breach of contract. Alternatively, MD Anderson brings an action for quantum meruit, promissory estoppel, unjust enrichment, negligent misrepresentation and reformation. Adaptimmune provided its Original Answer, Affirmative Defenses, Special Exceptions and Counterclaims on January 22, 2025 denying all allegations of the MD Anderson petition and counterclaiming for breach of contract. MD Anderson filed a motion to dismiss Adaptimmune’s counterclaim, Special Exceptions and Original Answer to the counterclaim denying all allegations in the counterclaim on February 11, 2025.

The case has not yet proceeded to discovery stage and we do not believe there is any merit to the claims being brought by MD Anderson. As such, no provision for a loss contingency has been made as of December 31, 2024.

*Other obligations*

On August 26, 2019, we entered into a collaboration and license agreement relating to the development of next-generation T-cell products with Noile-Immune Biotech, Inc. An upfront exclusive license option fee of \$2.5 million was paid to Noile-Immune in 2019. This has been recognized within Research and Development in the Consolidated Statement of Operations for the year ended December 31, 2019. Under the agreement, development and commercialization milestone payments up to a maximum of \$312 million may be payable if all possible targets are selected and milestones achieved. Noile-Immune would also receive mid-single-digit percentage royalties on net sales of resulting products.

On May 14, 2019, we entered into a Collaboration Agreement relating to the development of next-generation T-cell products with Alpine. We paid an upfront exclusive license option fee of \$2.0 million to Alpine in June 2019. Under the agreement, Adaptimmune will pay Alpine for ongoing research and development funding costs and development and commercialization milestone payments up to a maximum of \$288 million, which may be payable if all possible targets are selected and milestones achieved. The upfront payment of \$2.0 million and the payments for ongoing research are recognized within Research and development. A further payment of \$1 million was paid and recognized within Research and development in the Consolidated Statement of Operations for the year ended December 31, 2022. Alpine would also receive low single-digit royalties on worldwide net sales of applicable products.

As part of the process of obtaining regulatory approval for its products, the Company entered into various agreements for the development of assays for commercial supply, some of which have milestone or other payments that trigger on or after regulatory approval is received from the FDA, and upon the occurrence of future sales or commercial usage of the respective assay.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. Our preparation of these

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consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

Our accounting policies are described in more detail in Note 2 to our consolidated financial statements. We do not believe any of our accounting policies were critical to the judgments and estimates used in the preparation of our financial statements in the year ended December 31, 2024.

**Other Accounting Policies, Judgments and Estimates**

For the years ended December 31, 2024 and 2023 these accounting policies were not considered to be critical to the judgments and estimates used in the preparation of our financial statements, but were considered to be so for the year ended December 31, 2022.

*Identification of performance obligations – research collaborations and related agreements*

When the Company enters into research collaboration agreements with customers, both new agreements and amendments to pre-existing agreements, these contracts typically include various promises to customers, both explicit and implicit. As the Company's research collaborations normally relate to early-stage research and development for novel cell therapies, they often include services, licenses and other promises to customers that the Company has not previously provided. As such, when the Company enters into a new collaboration with customers, an assessment is performed to determine both what the explicit promises in the contract are, which may or may not be indicated by the pricing structure of the contract, and whether the contract contains any implicit promises to the customer. This assessment involves judgment about what the substance of the collaboration with the customer is, what goods or services the customer is ultimately engaging with the Company for and which of those goods and services are distinct in the context of the contract.

The Company recognizes revenue as the identified performance obligations are satisfied, which occurs as the Company transfers the promised good or service. The Company transfers a promised good or services as the customer obtains control of the good or service. The nature of the performance obligation and the Company's promise to the customer will determine whether the performance obligation is satisfied, and therefore revenue recognized, over time or at a point in time. The Company recognizes revenue over time using a single measure of progress for each performance obligation that most faithfully depicts the Company's performance in transferring control of goods or services promised to the customer. This assessment requires judgement and involves consideration of both output and input methods to determine which measure is most appropriate for the performance obligation being satisfied. As the Company's collaboration agreements typically have multi-year terms or include performance obligations which are not expected to be settled in a short period of time, the timing of, and measure of progress for, when the Company satisfies performance obligations, can have a significant impact on how the Company recognizes revenue.

An exercise to identify performance obligations and determine how performance obligations are satisfied was required in the years ending December 31, 2024, and 2023 for the Galapagos Collaboration Agreement and the GSK Termination and Transfer Agreement, respectively, although the assessment for the Galapagos Collaboration Agreement in 2024 was not considered to be critical to the judgements used in the preparation of our financial statements.

*Allocation of transaction price using the relative standalone selling price*

Upfront and other payments included in the transaction price of a contract are allocated between performance obligations using the Company's best estimate of the relative standalone selling price of the performance obligation. The relative standalone selling price is estimated by determining the market values of development and license obligations. As these inputs are not directly observable, the estimate is determined considering all reasonably available information

including internal pricing objectives used in negotiating the contract, together with internal data regarding the cost and margin of providing services for each deliverable, taking into account the different stage of development of each development program and consideration of adjusted-market data from comparable arrangements, where applicable and available. This assessment involves judgment and could have a significant impact on the amount and timing of revenue recognition.

An assessment of the allocation of transaction price using the relative standalone selling price was required in the years ended December 31, 2024 and 2023 for the Galapagos Collaboration Agreement and the GSK Termination and Transfer Agreement, respectively, although the assessments were not considered to be critical to the judgements used in the preparation of our financial statements.

***Impairment of long-lived assets classified as held and used***

The determination of whether long-lived assets classified as held and used depends on whether the asset exhibits indicators of potential impairment, which includes changes in the business environment in which the Company operates that affect the asset and changes in the planned usage of the asset.

Long-lived assets classified as held and used are considered not recoverable if the carrying amount exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the asset. An impairment loss is recognized on such assets to the amount that the carrying amount of the asset exceeds its fair value.

The fair value of long-lived assets is calculated using an expected present value technique. The fair value methodology used will differ depending on the nature and potential usage of the asset that is impaired. These approaches use a variety of inputs including external market data and price quotes and internal forecasts of the cash inflows and outflows that could be generated from the usage or disposition of the asset. This estimate involves significant judgment and could have a significant impact on the recognition and amount of impairment losses.

An assessment of fair value of various long-lived assets, primarily right-of-use and leasehold assets relating to the Company's facilities, was required in the year ended December 31, 2024 following the restructuring announced in November 2024.

***Operating Leases (Incremental Borrowing Rate)***

Since the rates implicit in our leases are not readily determinable, we use the Company's incremental borrowing rates (the rate of interest that we would have to pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments in a similar economic environment) based on the information available at commencement date in determining the discount rate used to calculate the present value of lease payments. As our external borrowings are not collateralized directly on equivalent assets, the incremental borrowing rates are determined using information on indicative borrowing rates that would be available to us based on the value, currency and borrowing term provided by financial institutions, adjusted for company and market specific factors.

Although we do not expect our estimates of the incremental borrowing rates to generate material differences within a reasonable range of sensitivities, judgement is involved in selecting an appropriate rate, and the rate selected for each lease will have an impact on the value of the lease liability and corresponding right-of-use (ROU) asset in the Consolidated Balance Sheets.

***Deferred Taxes***

Deferred tax is accounted for using the asset and liability method that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amount and the tax bases of assets and liabilities at the applicable tax rates. As of December 31, 2024, we have deferred tax assets of \$313.1 million, offset by deferred tax liabilities of \$3.6 million and a valuation allowance of \$309.5 million.

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A valuation allowance is provided when it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. Future realization of the tax benefit of a deferred tax asset depends on the existence of sufficient taxable income of the appropriate character (for example, ordinary income or capital gain) within the carryback or carryforward period available under the tax law. The Company considers the following possible sources of taxable income when assessing whether there is sufficient taxable income to realize a tax benefit for deductible temporary differences and carryforwards:

- future reversals of existing taxable temporary differences;
- future taxable income exclusive of reversing temporary differences and carryforwards;
- taxable income in prior carryback year(s) if carryback is permitted under the tax law; and
- tax-planning strategies.

The Company considers both positive and negative evidence regarding realization of the deferred tax assets and the subjectivity of this evidence. This assessment includes estimating future taxable income, scheduling reversals of temporary differences, evaluating expectations of future profitability, determining refund potential in the event of net operating loss carrybacks, and evaluating potential tax-planning strategies.

The Company has generated losses in the United Kingdom since inception and is forecasted to generate tax losses for the next several years and therefore the deferred tax assets arising in the United Kingdom are only considered more-likely-than-not of being realized to the extent that reversing temporary taxable differences are available.

TCR<sup>2</sup> has incurred net losses since acquisition and generates research and development tax credits. No net deferred tax assets are recognized on TCR<sup>2</sup>'s losses and tax credit carryforwards because there is currently no indication that we will make sufficient taxable profits to utilize these tax losses and tax credit carryforwards.

Adaptimmune LLC has generated taxable income since the fiscal year ended June 30, 2014 due to a Service Agreement between our U.S. and U.K. operating subsidiaries and is forecast to generate taxable income in future periods from this agreement and commercial sales of our products. In determining whether the deferred tax asset is more-likely-than-not of being recognized, the Company has taken into account the recent history of taxable profits, the forecast of future taxable income, including whether future originating temporary deductible differences are likely to be realized, and the reversal of temporary taxable deductions. Several of the temporary deductible differences reverse over a long time period, such as those relating to share-based compensation expense, which the Company forecasts are likely to reverse over the next five years. The Company considers that forecasting taxable income beyond the next few years is very subjective due to the nature and extent of the development process subcontracted from the Company in the United Kingdom to Adaptimmune LLC and the level of future commercial product sales. Less weight has been given to forecasts of taxable income beyond the next few years.

The Company's analysis is subject to estimates and judgments particularly relating to the timing of the reversal of temporary deductible differences for stock compensation expense and the availability of future taxable income beyond the next few years, which depend on the nature and extent of the subcontract development work performed by Adaptimmune LLC.

The deferred tax asset arising in Adaptimmune LLC is only considered more-likely-than-not of being realized to the extent that there are available reversing temporary taxable differences. As there is substantial doubt over whether the Company is a going concern, the Company considered Adaptimmune LLC's future taxable income over the period that our cash, cash equivalents and marketable securities are expected to fund our currently anticipated research, development and commercial activities and planned capital spending. Based on this assessment, the Company determined that there is not sufficient objectively verifiable positive evidence of future taxable income exclusive of reversing temporary differences and carryforwards that Adaptimmune LLC will generate each year such that it would be more-likely-than-not that the current deferred tax asset in the Adaptimmune LLC may be utilized. Therefore, the



Company concluded that a full valuation allowance should be maintained against the deferred tax asset of Adaptimmune LLC.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations, foreign currency exchange rate fluctuations, particularly between pound sterling and U.S. dollar, and credit risk. These risks are managed by maintaining an appropriate mix of cash deposits and securities in various currencies, placed with a variety of financial institutions for varying periods according to expected liquidity requirements.

As of December 31, 2024, we held \$60.5 million in marketable securities, with the aim of diversifying our investments and reducing credit risks. We have not entered into investments for trading or speculative purposes.

##### **Interest Rate Risk**

Our surplus cash and cash equivalents are invested in interest-bearing savings, money market funds, corporate, government and agency debt securities and bonds and commercial paper from time to time. Our investments in debt securities are subject to fixed interest rates. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.K. and U.S. bank interest rates and the fair market value of our corporate debt securities will fall in value if market interest rates increase. Our borrowings are subject to a variable interest rate if the Prime Rate increases above a contractual minimum but are effectively fixed if the Prime Rate is below this level. The Prime Rate is currently below our contractual minimum.

We do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

##### **Currency Risk**

We are exposed to foreign exchange rate risk because we currently operate in the United Kingdom and the United States. Our expenses are generally denominated in the currency in which our operations are located, which are the United Kingdom and the United States. However, our U.K.-based subsidiary incurs significant research and development costs in U.S. dollars and, to a lesser extent, Euros.

The results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. We seek to minimize this exposure by maintaining currency cash balances at levels appropriate to meet forthcoming expenses in U.S. dollars and pounds sterling. To date, we have not used forward exchange contracts or other currency hedging products to manage our exchange rate exposure, although we may do so in the future. The exchange rate as of December 31, 2024, the last business day of the reporting period, was £1.00 to \$1.25.

##### **Credit Risk**

Our cash and cash equivalents are held with multiple banks and we monitor the credit rating of those banks. Our investments in corporate debt securities and commercial paper are subject to credit risk. Our investment policy limits investments to certain types of instruments, such as money market instruments, corporate debt securities and commercial paper, places restrictions on maturities and concentration by type and issuer and specifies the minimum credit ratings for all investments and the average credit quality of the portfolio.

Trade receivables were \$1.5 million and \$0.8 million as of December 31, 2024 and 2023, respectively. Trade receivables arise in relation to the Astellas Collaboration Agreement, the Galapagos Collaboration and License

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Agreement, the Genentech Strategic Collaboration and License Agreement and the GSK Termination and Transfer Agreement and from commercial product sales. We have been transacting with Galapagos since May 2024, Genentech since October 2021, Astellas since January 2020 and GSK since 2014 and have been selling products commercially since November 2024, during which time no credit losses have been recognized. No balances were past due as of December 31, 2024. As of December 31, 2024, no allowance for expected credit losses is recognized on the basis that the possibility of credit losses arising on its receivables as of December 31, 2024 was deemed to be remote.

**Inflation risk**

Inflation may generally affect us by increasing our cost of labor and research and development expenses. While we have experienced increased operating expenses in recent periods, which we believe are due in part to the recent growth in inflation, we do not believe that inflation has had a material effect on our business, financial condition or results of operations during the year ended December 31, 2024; however, operating expenses may continue to increase in future periods due to inflation.

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

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

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

None

**Item 9A. Controls and Procedures**

**Management’s Report Regarding the Effectiveness of Disclosure Controls and Procedures.**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at December 31, 2024.

**Management’s Annual 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 Securities Exchange Act Rule 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission

Management has concluded that our internal control over financial reporting was effective at December 31, 2024. Management has also concluded that our audited financial statements included in this Report are fairly stated in all material respects in accordance with GAAP for each of the periods presented therein.

**Changes in Internal Control Over Financial Reporting.**

We have added additional internal control over financial reporting relating to inventory for TECELRA commercialization. Other than that there has been no material change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the fourth quarter of 2024 that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

**Item 9B. Other Information**

During the three-month period ended December 31, 2024, none of our directors or officers adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” as such terms are defined in Item 408(a) of Regulation S-K.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

**Insider Trading Policy**

The Company has adopted an insider trading policy governing the purchase, sale and other disposition of the Company’s securities, which includes a provision that restricts our directors, officers, and employees from engaging in hedging or monetization transactions involving our securities and from engaging in short sales of our securities. Our insider trading policy also prohibits our directors, officers, and employees from holding our securities in margin accounts or otherwise pledging our securities as collateral for loans. A copy of our insider trading policy is included as Exhibit 19.1 to this Annual Report.

**Clawback Policy**

While the Company does not presently have in place any significant incentive compensation agreements or awards related to the Company’s overall financial performance, the Company’s board of directors has adopted a clawback policy in order to comply with federal securities laws. As such, we have adopted a clawback policy in which we may seek the recovery and/or forfeiture of incentive compensation paid by us, including cash, equity or equity-based compensation, in the event that we restate our financial statements under certain circumstances. The clawback policy applies to our current and former officers. A copy of our clawback policy is included as Exhibit 97.1 to this Annual Report.

**Item 11. Executive Compensation**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

**Item 14. Principal Accounting Fees and Services**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

**(a) 1. Financial Statements**

As part of this Annual Report on Form 10-K, the consolidated financial statements are listed in the accompanying index to financial statements on page F-1.

**2. Financial Statement Schedules**

All schedules have been omitted because they are not required, not applicable, not present in amounts sufficient to require submission of the schedule, or the required information is otherwise included.

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**3. Exhibit Index**

The following is a list of exhibits filed as part of this Annual Report on Form 10-K or are incorporated herein by reference:

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
2.1†	<a href="#">Agreement and Plan of Merger, dated as of March 5, 2023, by and among Adaptimmune Therapeutics plc, CM Merger Sub, Inc. and TCR<sup>2</sup> Therapeutics Inc. (incorporated by reference to Exhibit 2.1 to our Form 8-K filed with the SEC on March 6, 2023).</a>
2.2	<a href="#">Amendment No. 1 to Agreement and Plan of Merger, dated as of April 5, 2023, by and among Adaptimmune, CM Merger Sub, Inc. and TCR<sup>2</sup> (incorporated by reference to Exhibit 2.2 to our Registration Statement on Form S-4 (file no. 333-271145)).</a>
3.1	<a href="#">Articles of Association of Adaptimmune Therapeutics plc (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the SEC on June 16, 2016).</a>
4.1	<a href="#">Form of certificate evidencing ordinary shares (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form F-1 (file no: 333-203267)).</a>
4.2	<a href="#">Form of Deposit Agreement among Adaptimmune Therapeutics plc, Citibank, N.A., as the depository bank and Holders and Beneficial Owners of ADSs issued thereunder (incorporated by reference to Exhibit 4.2 to our Registration Statement on Form F-1 (file no: 333-203267)).</a>
4.3	<a href="#">Form of American Depositary Receipt (included in Exhibit 4.2) (incorporated by reference to Exhibit 4.3 to our Registration Statement on Form F-1 (file no: 333-203267)).</a>
4.4	<a href="#">Description of the Registrant's Securities (incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 6, 2024).</a>
10.1†	<a href="#">Collaboration Agreement, dated January 5, 2018, between Adaptimmune Limited and Cell Therapy Catapult Limited (incorporated by reference to Exhibit 10.1 to our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).</a>
10.2†	<a href="#">Collaboration Agreement dated May 14, 2019 between Adaptimmune Limited and AIS Operating Co., Inc., f/k/a Alpine Immune Sciences, Inc. (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on August 1, 2019).</a>
10.3†	<a href="#">Collaboration agreement dated as of August 26, 2019, by and between Adaptimmune Limited and Noile-Immune Biotech, Inc. (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 27, 2019).</a>
10.4†	<a href="#">Collaboration and License Agreement, dated January 13, 2020, by and between Universal Cells, Inc. and Adaptimmune Limited (incorporated by reference to Exhibit 10.4 to our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 27, 2020).</a>
10.5†	<a href="#">Amended and Restated Research Collaboration and License Agreement, dated January 13, 2020, by and between Adaptimmune Limited and Universal Cells, Inc. and effective as of November 25, 2015 (incorporated by reference to Exhibit 10.5 to our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 27, 2020).</a>

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<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.6†	<a href="#"><u>First Amendment to Commercial Development and Supply Agreement, dated November 23, 2019, between Adaptimmune Limited and Life Technologies Corporation and effective as of November 18, 2019 (incorporated by reference to Exhibit 10.6 to our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on February 27, 2020).</u></a>
10.7†	<a href="#"><u>Commercial Development and Supply Agreement, dated June 16, 2016, by and between Life Technologies Corporation and Adaptimmune Limited and effective as of June 1, 2016 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on June 21, 2016).</u></a>
10.8†	<a href="#"><u>Strategic Alliance Agreement, dated September 23, 2016, by and between Adaptimmune LLC and The University Of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.11 to our Form 10-Q filed with the SEC on November 10, 2016).</u></a>
10.10	<a href="#"><u>Employment Agreement dated as of December 16, 2020 by and between Adaptimmune, LLC and Elliot Norry, and effective January 1, 2021, (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on December 16, 2020).</u></a>
10.11	<a href="#"><u>Employment Agreement dated as of August 1, 2019 by and between Adaptimmune, LLC and John Lunger (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 1, 2019).</u></a>
10.12	<a href="#"><u>Employment Agreement dated as of June 26, 2019 by and between Adaptimmune, LLC and Adrian Rawcliffe (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on June 27, 2019).</u></a>
10.13	<a href="#"><u>Letter of Appointment dated July 5, 2018 and effective from July 5, 2018 between the Company and John Furey (incorporated by reference to Exhibit 99.1 to our Form 8-K filed with the SEC on July 6, 2018).</u></a>
10.14	<a href="#"><u>Employment Agreement dated as of March 15, 2017 by and between Adaptimmune, LLC and William Bertrand (incorporated by reference to Exhibit 99.2 to our Form 8-K filed with the SEC on March 15, 2017).</u></a>
10.15	<a href="#"><u>Service Agreement dated March 15, 2017 between Adaptimmune Limited and Helen Tayton-Martin (incorporated by reference to Exhibit 99.3 to our Form 8-K filed with the SEC on March 15, 2017).</u></a>
10.16	<a href="#"><u>Executive Severance policy of Adaptimmune Therapeutics plc, dated March 10, 2017, and effective March 10, 2017 (incorporated by reference to Exhibit 10.21 to our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 13, 2017).</u></a>
10.16.1	<a href="#"><u>Executive Severance Policy of Adaptimmune Therapeutics plc dated March 10, 2017 and amended and restated effective as of June 11, 2024 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on June 11, 2024).</u></a>
10.16.2	<a href="#"><u>Executive Severance Policy of Adaptimmune Therapeutics plc dated March 10, 2017 and amended and restated effective as of June 11, 2024 and on July 16, 2024 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on July 16, 2024).</u></a>

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<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.17	<a href="#">Letter of Appointment, dated August 9, 2016 and effective August 11, 2016, between the Company and David M. Mott (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 12, 2016).</a>
10.18	<a href="#">Letter of Appointment, dated August 9, 2016 and effective August 11, 2016, between the Company and Lawrence M. Alleva (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on August 12, 2016).</a>
10.19	<a href="#">Letter of Appointment, dated August 9, 2016 and effective August 11, 2016, between the Company and Ali Behbahani (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on August 12, 2016).</a>
10.20	<a href="#">Service Agreement dated February 17, 2020, between Adaptimmune Limited and Gavin Wood, and effective April 1, 2020, (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on February 18, 2020).</a>
10.21	<a href="#">Adaptimmune Therapeutics plc Company Share Option Plan, dated March 16, 2015, as amended on April 15, 2015, as further amended on January 13, 2016 (incorporated by reference to Exhibit 4.32 to our Transition Report on Form 20-F filed with the SEC on March 17, 2016).</a>
10.22	<a href="#">Adaptimmune Therapeutics plc 2015 Share Option Scheme, dated March 16, 2015, as amended on April 15, 2015, January 13, 2016, December 18, 2017 and June 29, 2023 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on June 29, 2023).</a>
10.23	<a href="#">Adaptimmune Therapeutics plc 2016 Employee Share Option Scheme, dated January 14, 2016, as amended on December 18, 2017 and June 29, 2023 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on June 29, 2023).</a>
10.24	<a href="#">Adaptimmune Limited Share Option Scheme (Incorporating Management Incentive Options), as amended on January 13, 2016 (incorporated by reference to Exhibit 4.28 to our Transition Report on Form 20-F filed with the SEC on March 17, 2016).</a>
10.25	<a href="#">Adaptimmune Limited 2014 Share Option Scheme (Incorporating Enterprise Management Incentive Options), as amended on January 13, 2016 (incorporated by reference to Exhibit 4.29 to our Transition Report on Form 20-F filed with the SEC on March 17, 2016).</a>
10.26	<a href="#">Adaptimmune Limited Company Share Option Plan, dated December 16, 2014, as amended on January 13, 2016 (incorporated by reference to Exhibit 4.30 to our Transition Report on Form 20-F filed with the SEC on March 17, 2016).</a>
10.27	<a href="#">Deed of Variation, dated August 20, 2021, between MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited and Adaptimmune Limited relating to a lease of 39 Innovation Drive, Milton Park (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 20, 2021).</a>

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<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.28	<a href="#">Rent Security Deposit Deed dated August 20, 2021, between MEPC Milton Park No 1 Limited and MEPC Milton Park No. 2 Limited, Adaptimmune Limited and Adaptimmune Therapeutics plc relating to 39 Innovation Drive and 60 Jubilee Avenue, Milton Park (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on August 20, 2021).</a>
10.29	<a href="#">Agreement dated August 13, 2021, between MEPC Milton Park No 1 Limited and MEPC Milton Park No. 2 Limited, Adaptimmune Limited and Adaptimmune Therapeutics plc relating to 39 Innovation Drive and 60 Jubilee Avenue, Milton Park (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 13, 2021).</a>
10.30	<a href="#">Deed of Variation dated August 13, 2021, between MEPC Milton Park No 1 Limited and MEPC Milton Park No. 2 Limited, Adaptimmune Limited and Adaptimmune Therapeutics plc relating to a lease of 60 Jubilee Avenue, Milton Park (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 13, 2021).</a>
10.31	<a href="#">Lease, dated February 28, 2018, between MEPC Milton Park No. 1 Limited, MEPC Milton Park No. 2 Limited and Adaptimmune Limited relating to 39 Innovation Drive, Milton Park (incorporated by reference to Exhibit 10.3 to our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).</a>
10.32	<a href="#">Rent Security Deposit Deed, dated February 28, 2018, between MEPC Milton Park No. 1 Limited, MEPC Milton Park No. 2 Limited and Adaptimmune Limited relating to 39 Innovation Drive, Milton Park (incorporated by reference to Exhibit 10.4 to our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).</a>
10.33	<a href="#">Lease, dated October 24, 2016, by and between MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, Adaptimmune Limited and Adaptimmune Therapeutics plc relating to 60 Jubilee Avenue Milton Park (incorporated by reference to Exhibit 10.12 to our Form 10-Q filed with the SEC on November 10, 2016).</a>
10.34	<a href="#">Lease Agreement, dated July 28, 2015, between L/S 351 Rouse Boulevard, LP, and Adaptimmune LLC relating to 351 Rouse Boulevard, Philadelphia, Pennsylvania (incorporated by reference to Exhibit 4.14 to our Transition Report on Form 20-F filed with the SEC on October 13, 2015).</a>
10.35	<a href="#">Employment Agreement dated as of May 4, 2022 by and between Adaptimmune Limited and Joanna Brewer (incorporated by reference to Exhibit 10.1 to our Form 8-K Filed with the SEC on May 4, 2022).</a>
10.36	<a href="#">Deed of Surrender of Part dated June 15, 2022, between MEPC Milton Park No 1 Limited and MEPC Milton Park No. 2 Limited and Adaptimmune Limited relating to a lease of 39 Innovation Drive, Milton Park (incorporated by reference to Exhibit 10.1 to our Form 8-K Filed with the SEC on June 15, 2022).</a>
10.37	<a href="#">Deed of Variation dated June 15, 2022, between MEPC Milton Park No 1 Limited and MEPC Milton Park No. 2 Limited and Adaptimmune Limited relating to a lease of 39 Innovation Drive, Milton Park (incorporated by reference to Exhibit 10.2 to our Form 8-K Filed with the SEC on June 15, 2022).</a>
10.38	<a href="#">Letter of Appointment dated February 15, 2023 between Adaptimmune Therapeutics plc and Kristen Hege (incorporated by reference to Exhibit 10.1 to our Form 8-K, filed with the SEC on February 16, 2023).</a>



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<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.39	<a href="#">Letter of Appointment, dated June 1, 2023, by and between Adaptimmune and Andrew Allen (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on June 1, 2023).</a>
10.40	<a href="#">Letter of Appointment, dated June 1, 2023, by and between Adaptimmune and Priti Hegde (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on June 1, 2023).</a>
10.41	<a href="#">Letter of Appointment, dated June 1, 2023, by and between Adaptimmune and Garry Menzel (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the SEC on June 1, 2023).</a>
10.42	<a href="#">Employment Agreement dated February 26, 2024 by and between Adaptimmune, LLC and Cintia Piccina. (incorporated by reference to exhibit 10.1 to our Form 8-K filed with the SEC on February 27, 2024).</a>
10.43†	<a href="#">Loan and Security Agreement, dated May 14, 2024, by and among Adaptimmune Therapeutics plc, Adaptimmune LLC, CM Intermediate Sub I, Inc., CM Intermediate Sub II, Inc., TCR2 Therapeutics Inc., TRUCS Therapeutics Limited, Adaptimmune Limited and Hercules Capital, Inc. (incorporated by reference to exhibit 10.1 to our Form 10-Q filed with the SEC on August 12, 2024).</a>
10.44†	<a href="#">Collaboration and Exclusive License Agreement, dated May 30, 2024, by and among Adaptimmune Limited and Galapagos NV. (incorporated by reference to exhibit 10.2 to our Form 10-Q filed with the SEC on August 12, 2024).</a>
10.45	<a href="#">Lease Agreement, dated as of June 30, 2017, by and between ARE-MA Region No. 45, LLC and TCR2 Therapeutics Inc. (incorporated by reference to Exhibit 10.7 to TCR2 Therapeutics Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 23, 2023).</a>
19.1	<a href="#">Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 6, 2024).</a>
21.1*	<a href="#">List of Subsidiaries.</a>
23.1*	<a href="#">Consent of KPMG LLP</a>
31.1*	<a href="#">Certificate of Chief Executive Officer pursuant to 17 CFR 240.13a-14(a).</a>
31.2*	<a href="#">Certificate of Chief Financial Officer pursuant to 17 CFR 240.13a-14(a).</a>
32.1*	<a href="#">Certificate of Chief Executive Officer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C.1350.</a>
32.2*	<a href="#">Certificate of Chief Financial Officer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C.1350.</a>
97.1	<a href="#">Clawback Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 6, 2024).</a>
101.INS*	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.

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<b>Exhibit Number</b>	<b>Description of Exhibit</b>
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

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\* Filed herewith.

† Confidential treatment has been granted with respect to portions of this exhibit. A complete copy of this exhibit, including the redacted terms, has been filed separately with the Securities and Exchange Commission.

**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, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized, on March 24, 2025.

ADAPTIMMUNE THERAPEUTICS PLC

By: /s/ Adrian Rawcliffe

Name: Adrian Rawcliffe

Title: Chief Executive Officer and Director

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Adrian Rawcliffe and Gavin Wood, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all 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 connection therewith, 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 any of them or their or his 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 by the following persons on March 24, 2025, in the capacities indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Adrian Rawcliffe</u> Adrian Rawcliffe	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 24, 2025
<u>/s/ Gavin Wood</u> Gavin Wood	Chief Financial Officer <i>(Principal Accounting and Financial Officer)</i>	March 24, 2025
<u>/s/ David M. Mott</u> David M. Mott	Chairman of the Board of Directors	March 24, 2025
<u>/s/ Andrew Allen, MD, PhD</u> Andrew Allen, MD, PhD	Director	March 24, 2025
<u>/s/ Lawrence M. Alleva</u> Lawrence M. Alleva	Director	March 24, 2025
<u>/s/ Ali Behbahani, MD</u> Ali Behbahani, MD	Director	March 24, 2025
<u>/s/John Furey</u> John Furey	Director	March 24, 2025
<u>/s/ Priti Hegde, PhD</u> Priti Hegde, PhD	Director	March 24, 2025
<u>/s/ Kristen M. Hege, MD</u> Kristen M. Hege, MD	Director	March 24, 2025
<u>/s/ Garry Menzel, PhD</u> Garry Menzel, PhD	Director	March 24, 2025

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

### To the Stockholders and Board of Directors of Adaptimmune Therapeutics plc:

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

We have audited the accompanying consolidated balance sheets of Adaptimmune Therapeutics plc and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated 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 years in the three-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

#### *Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise 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 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### *Critical Audit Matters*

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2010.

Reading, United Kingdom  
March 24, 2025

**ADAPTIMMUNE THERAPEUTICS PLC**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share data)

	December 31, 2024	December 31, 2023
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 91,139	\$ 143,991
Marketable securities - available-for-sale debt securities (amortized cost of \$60,451 and \$2,940) net of allowance for expected credit losses of \$0 and \$0	60,466	2,947
Accounts receivable, net of allowance for expected credit losses of \$0 and \$0	1,454	821
Inventory, net	7,320	—
Other current assets and prepaid expenses	27,790	59,793
<b>Total current assets</b>	<b>188,169</b>	<b>207,552</b>
Restricted cash	2,067	3,026
Other non-current assets	629	—
Operating lease right-of-use assets, net of accumulated amortization of \$17,750 and \$13,220	19,909	20,762
Property, plant and equipment, net of accumulated depreciation of \$51,893 and \$46,020	31,309	50,946
Intangible assets, net of accumulated amortization of \$5,567 and \$5,155	3,880	330
<b>Total assets</b>	<b>\$ 245,963</b>	<b>\$ 282,616</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 8,692	\$ 8,128
Operating lease liabilities, current	4,709	5,384
Accrued expenses and other current liabilities	32,919	30,303
Restructuring provision	5,911	—
Deferred revenue, current	12,296	28,973
<b>Total current liabilities</b>	<b>64,527</b>	<b>72,788</b>
Operating lease liabilities, non-current	19,263	19,851
Deferred revenue, non-current	95,815	149,060
Borrowings, non-current	50,237	—
Other liabilities, non-current	4,272	1,404
<b>Total liabilities</b>	<b>234,114</b>	<b>243,103</b>
<b>Stockholders' equity</b>		
Common stock - Ordinary shares par value £0.001, 2,039,252,874 authorized and 1,535,653,620 issued and outstanding (2023: 1,702,760,280 authorized and 1,363,008,102 issued and outstanding)	2,085	1,865
Additional paid in capital	1,105,653	1,064,569
Accumulated other comprehensive loss	(1,902)	(3,748)
Accumulated deficit	(1,093,987)	(1,023,173)
<b>Total stockholders' equity</b>	<b>11,849</b>	<b>39,513</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 245,963</b>	<b>\$ 282,616</b>

See accompanying notes to Consolidated Financial Statements.

**ADAPTIMMUNE THERAPEUTICS PLC**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)

	Year Ended		
	December 31, 2024	December 31, 2023	December 31, 2022
<b>Revenue:</b>			
Product revenue, net	\$ 1,236	\$ —	\$ —
Development revenue	176,796	60,281	27,148
<b>Total revenue</b>	<b>178,032</b>	<b>60,281</b>	<b>27,148</b>
<b>Operating expenses:</b>			
Cost of goods sold	(70)	—	—
Research and development	(149,060)	(126,509)	(127,726)
Selling, general and administrative	(87,261)	(73,513)	(63,387)
Impairment of long-lived assets	(10,401)	—	—
<b>Total operating expenses</b>	<b>(246,792)</b>	<b>(200,022)</b>	<b>(191,113)</b>
<b>Loss from operations</b>	<b>(68,760)</b>	<b>(139,741)</b>	<b>(163,965)</b>
Interest income	6,596	5,964	1,542
Interest expense	(3,348)	—	—
Gain on bargain purchase	—	22,049	—
Other income (expense), net	(1,726)	(807)	(536)
<b>Loss before income tax expense</b>	<b>(67,238)</b>	<b>(112,535)</b>	<b>(162,959)</b>
Income tax expense	(3,576)	(1,336)	(2,497)
<b>Net loss attributable to ordinary shareholders</b>	<b>\$ (70,814)</b>	<b>\$ (113,871)</b>	<b>\$ (165,456)</b>
<b>Net loss per ordinary share</b>			
Basic and diluted net loss per share	\$ (0.05)	\$ (0.09)	\$ (0.17)
<b>Weighted average shares outstanding:</b>			
Basic and diluted	1,513,810,852	1,206,440,978	967,242,403

See accompanying notes to Consolidated Financial Statements.

**ADAPTIMMUNE THERAPEUTICS PLC**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(in thousands)**

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
<b>Net loss</b>	<b>\$ (70,814)</b>	<b>\$ (113,871)</b>	<b>\$ (165,456)</b>
<b>Other comprehensive (loss)/income, net of tax</b>			
Foreign currency translation adjustments, net of tax of \$0, \$0 and \$0	10,470	(37,921)	60,421
Foreign currency (losses)/gains on intercompany loan of a long-term investment nature, net of tax of \$0, \$0 and \$0	(8,635)	34,112	(49,581)
Unrealized holding gains/ (losses) on available-for-sale debt securities, net of tax of \$0, \$0 and \$0	11	1,134	(573)
Reclassification adjustment for loss on available-for-sale debt securities included in net loss, net of tax of \$0, \$0, and \$0	—	(198)	—
<b>Total comprehensive loss for the period</b>	<b>\$ (68,968)</b>	<b>\$ (116,744)</b>	<b>\$ (155,189)</b>

See accompanying notes to Consolidated Financial Statements.



**ADAPT IMMUNE THERAPEUTICS PLC**  
**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**  
(in thousands, except share data)

	Common stock	Common stock	Additional paid in capital	Accumulated other comprehensive (loss) income	Accumulated deficit	Total stockholders' equity
<b>Balance as of January 1, 2022</b>	<u>937,547,934</u>	<u>\$ 1,337</u>	<u>\$ 959,611</u>	<u>\$ (11,142)</u>	<u>\$ (743,846)</u>	<u>\$ 205,960</u>
Issuance of shares upon exercise of stock options	5,823,534	8	42	—	—	50
Issue of shares under At The Market sales agreement, net of commission and expenses	43,738,422	54	12,763	—	—	12,817
Other comprehensive income	—	—	—	10,267	—	10,267
Share-based compensation expense	—	—	18,240	—	—	18,240
Net loss	—	—	—	—	(165,456)	(165,456)
<b>Balance as of December 31, 2022</b>	<u>987,109,890</u>	<u>\$ 1,399</u>	<u>\$ 990,656</u>	<u>\$ (875)</u>	<u>\$ (909,302)</u>	<u>\$ 81,878</u>
Issuance of shares upon exercise of stock options	14,614,410	18	238	—	—	256
Issue of shares under At The Market sales agreement, net of commission and expenses	3,854,496	5	619	—	—	624
Other comprehensive loss	—	—	—	(2,873)	—	(2,873)
Share-based compensation expense	—	—	12,736	—	—	12,736
Issuance of shares upon acquisition of TCR <sup>2</sup>	357,429,306	443	60,320	—	—	60,763
Net loss	—	—	—	—	(113,871)	(113,871)
<b>Balance as of December 31, 2023</b>	<u>1,363,008,102</u>	<u>1,865</u>	<u>1,064,569</u>	<u>(3,748)</u>	<u>(1,023,173)</u>	<u>39,513</u>
Issuance of shares upon exercise of stock options	8,976,462	11	66	—	—	77
Issue of shares under At The Market sales agreement, net of commission and expenses	163,669,056	209	28,963	—	—	29,172
Other comprehensive income	—	—	—	1,846	—	1,846
Share-based compensation expense	—	—	12,055	—	—	12,055
Net loss	—	—	—	—	(70,814)	(70,814)
<b>Balance as of December 31, 2024</b>	<u>1,535,653,620</u>	<u>\$ 2,085</u>	<u>\$ 1,105,653</u>	<u>\$ (1,902)</u>	<u>\$ (1,093,987)</u>	<u>\$ 11,849</u>

See accompanying notes to Consolidated Financial Statements.

**ADAPT IMMUNE THERAPEUTICS PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
<b>Cash flows from operating activities</b>			
Net loss	\$ (70,814)	\$ (113,871)	\$ (165,456)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>			
Depreciation	10,814	9,453	5,266
Amortization	411	387	809
Impairment of long-lived assets	10,401	—	—
Gain on bargain purchase	—	(22,049)	—
Share-based compensation expense	12,051	11,773	18,240
Unrealized foreign exchange losses	1,995	198	(2,438)
(Accretion)/amortization of available-for-sale debt securities	(1,267)	(1,986)	2,525
Other	182	167	816
<i>Changes in operating assets and liabilities:</i>			
Decrease/(increase) in receivables and other operating assets	29,765	(1,291)	(9,813)
Increase in inventories	(7,355)	—	—
Increase/(decrease) in payables and other current liabilities	9,619	(9,087)	4,408
Increase in noncurrent assets	(642)	—	—
Increase in borrowings and other non-current liabilities	1,429	—	—
(Decrease)/increase in deferred revenue	(69,795)	(14,574)	3,874
<b>Net cash used in operating activities</b>	<b>(73,206)</b>	<b>(140,880)</b>	<b>(141,769)</b>
<b>Cash flows from investing activities</b>			
Acquisition of property, plant and equipment	(886)	(4,681)	(29,496)
Acquisition of intangible assets	(1,834)	(199)	(244)
Cash from acquisition of TCR2 Therapeutics Inc.	—	45,264	—
Maturity or redemption of marketable securities	44,057	210,983	166,994
Investment in marketable securities	(100,418)	(75,953)	(48,117)
Other	129	1,124	—
<b>Net cash (used in)/provided by investing activities</b>	<b>(58,952)</b>	<b>176,538</b>	<b>89,137</b>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of borrowings, net of discount	49,500	—	—
Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	29,172	624	12,817
Proceeds from exercise of stock options	77	256	50
<b>Net cash provided by financing activities</b>	<b>78,749</b>	<b>880</b>	<b>12,867</b>
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(402)	877	(2,299)
Net decrease in cash, cash equivalents and restricted cash	(53,811)	37,415	(42,064)
Cash, cash equivalents and restricted cash at start of period	147,017	109,602	151,666
<b>Cash, cash equivalents and restricted cash at end of period</b>	<b>\$ 93,206</b>	<b>\$ 147,017</b>	<b>\$ 109,602</b>
<b>Supplemental cash flow information</b>			
Interest received	\$ 5,309	\$ 4,748	\$ 5,149
Interest paid	(2,092)	—	—
Accretion/(amortization) on available-for-sale debt securities	1,267	1,986	(2,525)
Income taxes paid	(1,525)	(4,000)	(630)

See accompanying notes to Consolidated Financial Statements.

**ADAPT IMMUNE THERAPEUTICS PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 — General**

Adaptimmune Therapeutics plc is registered in England and Wales. Its registered office is 60 Jubilee Avenue, Milton Park, Abingdon, Oxfordshire, OX14 4RX, United Kingdom. Adaptimmune Therapeutics plc and its subsidiaries (collectively “Adaptimmune” or the “Company”) is a commercial-stage biopharmaceutical company primarily focused on the treatment of solid tumor cancers with cell therapies. The Company’s proprietary platform enables it to identify cancer targets, find and develop cell therapy candidates active against those targets and produce therapeutic candidates for administration to patients.

The Company is subject to a number of risks similar to other biopharmaceutical companies in the early commercial and clinical development stages including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical programs or clinical programs, the need to obtain marketing approval for its cell therapies, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of its cell therapies, the need to develop a reliable commercial manufacturing process, the need to commercialize any cell therapies that may be approved for marketing, and protection of proprietary technology. If the Company does not successfully commercialize any of its cell therapies, it will be unable to generate product revenue or achieve profitability. Even though the Company has obtained marketing approval for its first cell therapy, TECELRA, it will take a period of time before any significant revenue is realized and the amount of revenue is heavily dependent on the success of commercialization and the costs of supplies including any post-marketing requirements the Company is subject to. The Company had an accumulated deficit of \$1,093,987,000 as of December 31, 2024.

**Note 2 — Summary of Significant Accounting Policies**

**(a) Basis of presentation**

The Consolidated Financial Statements of Adaptimmune Therapeutics plc and its subsidiaries and other financial information included in this Annual Report have been prepared in accordance with generally accepted accounting principles in the United States of America (“US GAAP”) and are presented in U.S. dollars. All significant intercompany accounts and transactions between the Company and its subsidiaries have been eliminated on consolidation.

**(b) Use of estimates in financial statements**

The preparation of financial statements, in conformity with U.S. GAAP and SEC regulations, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and reported amounts of revenues and expenses during the reporting period. Estimates and assumptions are primarily made in relation to revenue recognition, estimation of the incremental borrowing rate for operating leases, impairment of long-lived assets, restructuring costs and valuation allowances relating to deferred tax assets. If actual results differ from the Company’s estimates, or to the extent these estimates are adjusted in future periods, the Company’s results of operations could either benefit from, or be adversely affected by, any such change in estimate.

**(c) Going concern**

In accordance with Accounting Standards Codification (“ASC”) 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the financial statements are issued.

The Company has identified conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the financial statements are issued. The Company’s cash and cash equivalents are primarily used in its operating activities. As of December 31, 2024, the Company had cash, cash

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equivalents and marketable securities of \$151.6 million and used \$73.2 million cash in operating activities during the year ended December 31, 2024. The Company expects negative cash flows from operations to continue, for at least the next twelve months, as the ramp up of its commercialization of Tecelra continues.

Based on the Company's current cash and cash equivalents, anticipated cash outflows for operating and financing activities and likely cash inflows from customers, Management does not believe that the Company's existing cash, cash equivalents and marketable securities will be sufficient to fund its operating activities (including in relation to its obligations arising under the Loan Agreement) for at least the next 12 months from the filing date of this Annual Report on Form 10-K. As detailed further in Note 16, the Company is also subject to certain financial covenants under its Loan Agreement with Hercules Capital, including the maintenance of cash, cash equivalents and marketable securities to certain levels. If the Company's cash and cash equivalents and marketable securities fall below certain levels specified in the Hercules Capital Loan Agreement, this would result in a breach of the Company's financial covenants (as set out in Note 16). If the covenants with Hercules Capital are breached, then Hercules Capital may call in some or all of the outstanding principal (together with early repayment charge). The Company may have insufficient funds to repay the required amounts at the time that the amount becomes due despite having agreed to pre-pay \$25 million of existing loan under the Loan Agreement.

The Company intends to attempt to mitigate the conditions that give rise to substantial doubt over going concern through a combination of different activities. First the Company is taking immediate steps to reduce its operating costs. These steps include the deprioritization of the PRAME and ADP-520 programs and stopping or deferment of all non-essential operating expenses. Such steps will have a short-term impact on operating expenses and also a longer-term impact on the amount of funding required for activities in the medium term. Despite these steps, further sources of funding will still need to be identified and we are actively looking at a variety of strategic opportunities and have engaged TD Cowen to evaluate strategic options for the Company and all of its programs. These could include potential mergers with third parties, acquisitions of part or all of the business together with other collaborations or partnerships. We are also considering acquiring additional funding through use of the Company ATM and/or other methods of raising equity financing.

As detailed in Note 17, on November 13, 2024, the Company announced a restructuring program to deprioritize certain programs and reduce headcount, in order to reduce operating costs. Although these measures will reduce the Company's operating costs in the long term, they will not alleviate the conditions that give rise to the substantial doubt over going concern and the Company must acquire additional funding. Whilst the Company has had a successful record of financing the company through various means since its inception, including raising over \$1.4 billion through a combination of equity and business development activities, there is no assurance that the Company will be able to obtain sufficient additional capital to continue funding its operations or, if we do, that it will be on terms that are favorable to our shareholders.

If the Company fails to obtain additional funding, it will be required to do some or all of the following:

- further reduce operations of the business. Any such reduction could significantly delay the timelines under which we can bring new products to the market (including lete-cel) or our ability to commercialize Tecelra.
- conduct a further restructuring of the company to further reduce headcount and expenditure which will in turn reduce the activities and operations of the business.
- repay the remaining loan advance received under the Loan Agreement in accordance with the terms of the Loan Agreement (including any applicable repayment charges, end of term charges or other costs).
- seek an acquirer or alternative party for a merger for all or part of the business or its assets on terms that are less favorable than might otherwise be available
- relinquish or license on unfavorable terms or rights to technologies, intellectual property or product candidates we would otherwise seek to develop or commercialize ourselves.

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If the Company fails to obtain additional funding, or in the event that the Company further significantly reduces its ongoing expenditures and operations (including the current restructuring), this may result in an inability to retain the key individuals required for its ongoing business and may result in a need to delay or halt ongoing programs or change the nature and scope of such programs. As a result, our business financial condition and results of operations could be materially affected. Not all of the potential mitigating actions set out above are under the direct control of the Company and may rely on third parties to implement. The general macro-economic conditions and market and trading environment are also difficult to predict and could adversely affect our ability to put in place mitigating actions. As a result, there is substantial doubt over the Company's ability to continue as a going concern within 12 months from the date of filing of this Annual Report on Form 10-K and is not alleviated as of the date of filing.

The consolidated financial statements do not include any adjustments that might result from the Company not being able to alleviate the substantial doubt over going concern. As such, the consolidated financial statements have been prepared on the basis that assumes the Company will be able to continue as a going concern and will be able to fund its operations and satisfy its liabilities, obligations and commitments as they fall due within the ordinary course of business.

**(d) Foreign currency**

The reporting currency of the Company is the U.S. dollar. The Company has determined the functional currency of the ultimate parent company, Adaptimmune Therapeutics plc, is U.S. dollars because it predominately raises finance and expends cash in U.S. dollars. The functional currency of subsidiary operations is the applicable local currency. Transactions in foreign currencies are translated into the functional currency of the subsidiary in which they occur at the foreign exchange rate in effect on at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated into the functional currency of the relevant subsidiary at the foreign exchange rate in effect on the balance sheet date. Foreign exchange differences arising on translation are recognized within other income (expense) in the Consolidated Statement of Operations.

The Company's U.K. subsidiary has an intercompany loan balance in U.S. dollars payable to the ultimate parent company, Adaptimmune Therapeutics plc. Beginning on July 1, 2019, the intercompany loan was considered of a long-term investment nature as repayment is not planned or anticipated in the foreseeable future. It is Adaptimmune Therapeutics plc's intent not to request payment of the intercompany loan for the foreseeable future. The foreign exchange gain or losses arising on the revaluation of intercompany loans of a long-term investment nature are reported within other comprehensive (loss) income, net of tax.

The results of operations for subsidiaries, whose functional currency is not the U.S. dollar, are translated at an average rate for the period where this rate approximates to the foreign exchange rates ruling at the dates of the transactions and the balance sheet are translated at foreign exchange rates ruling at the balance sheet date. Exchange differences arising from this translation of foreign operations are reported as an item of other comprehensive (loss) income.

Foreign exchange losses for the years ended December 31, 2024, 2023, and 2022 of \$1,726,000, \$807,000 and \$536,000 respectively, are included within Other (expense) income, net in the Consolidated Statement of Operations.

**(e) Fair value measurements**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The hierarchy defines three levels of valuation inputs:

Level 1 — Quoted prices in active markets for identical assets or liabilities

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly

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Level 3 — Unobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability

The carrying amounts of the Company’s cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments. The fair value of marketable securities, which are measured at fair value on a recurring basis is detailed in Note 4, *Financial Instruments*.

**(f) Accumulated other comprehensive (loss) income**

The Company reports foreign currency translation adjustments and the foreign exchange gain or losses arising on the revaluation of intercompany loans of a long-term investment nature within Other comprehensive (loss) income. Unrealized gains and losses on available-for-sale debt securities are also reported within Other comprehensive (loss) income until a gain or loss is realized, at which point they are reclassified to Other (expense) income, net in the Consolidated Statement of Operations.

The following table shows the changes in Accumulated other comprehensive (loss) income (in thousands):

	Accumulated foreign currency translation adjustments	Accumulated unrealized (losses) gains on available-for-sale debt securities	Total accumulated other comprehensive (loss) income
Balance at January 1, 2022	\$ (10,785)	\$ (357)	\$ (11,142)
Foreign currency translation adjustments	60,421	—	60,421
Foreign currency losses on intercompany loan of a long-term investment nature, net of tax of \$0	(49,581)	—	(49,581)
Unrealized holding losses on available-for-sale debt securities, net of tax of \$0	—	(573)	(573)
<b>Balance at December 31, 2022</b>	<b>\$ 55</b>	<b>\$ (930)</b>	<b>\$ (875)</b>
Foreign currency translation adjustments	(37,921)	—	(37,921)
Foreign currency gains on intercompany loan of a long-term investment nature, net of tax of \$0	34,112	—	34,112
Unrealized holding gains on available-for-sale debt securities, net of tax of \$0	—	1,134	1,134
Reclassification from accumulated other comprehensive (loss) income of gains on available-for-sale debt securities included in net income, net of tax of \$0	—	(198)	(198)
<b>Balance at December 31, 2023</b>	<b>\$ (3,754)</b>	<b>\$ 6</b>	<b>\$ (3,748)</b>
Foreign currency translation adjustments	10,470	—	10,470
Foreign currency losses on intercompany loan of a long-term investment nature, net of tax of \$0	(8,635)	—	(8,635)
Unrealized holding gains on available-for-sale debt securities, net of tax of \$0	—	11	11
<b>Balance at December 31, 2024</b>	<b>\$ (1,919)</b>	<b>\$ 17</b>	<b>\$ (1,902)</b>

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The following amounts were reclassified out of Other comprehensive (loss) income (in thousands):

Component of accumulated other comprehensive income	Amount reclassified			Affected line item in the Statement of Operations
	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022	
<b>Unrealized gains on available-for-sale securities</b>				
Reclassification adjustment for gains on available-for-sale debt securities	\$ —	\$ (198)	\$ —	Other (expense) income, net

**(g) Cash, cash equivalents and restricted cash**

The Company considers all highly liquid investments with a maturity at acquisition date of three months or less to be cash equivalents. Cash and cash equivalents comprise cash balances, commercial paper and corporate debt securities with maturities of three months or less at acquisition and short deposits with maturities of three months or less.

The Company's restricted cash consists primarily of cash providing security for letters of credit in respect of lease agreements and credit cards.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same such amounts shown in the statement of cash flows (in thousands).

	December 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 91,139	\$ 143,991
Restricted cash	2,067	3,026
<b>Total cash, cash equivalents, and restricted cash shown in the statement of cash flows</b>	<b>\$ 93,206</b>	<b>\$ 147,017</b>

**(h) Available-for-sale debt securities**

As of December 31, 2024, the Company has the following investments in available-for-sale debt securities, (in thousands):

	Remaining contractual maturity	Amortized cost	Gross unrealized gains	Gross unrealized losses	Aggregate estimated fair value
<b>Cash equivalents:</b>					
U.S. Treasury securities	Less than 3 months	\$ 8,946	\$ 2	\$ —	\$ 8,948
		<u>\$ 8,946</u>	<u>\$ 2</u>	<u>\$ —</u>	<u>\$ 8,948</u>
<b>Available-for-sale debt securities:</b>					
Agency bonds	Less than 3 months	\$ 7,012	\$ 3	\$ —	\$ 7,015
Corporate debt securities	Less than 3 months	2,021	—	—	2,021
U.S. Treasury securities	Less than 3 months	44,271	14	—	44,285
Corporate debt securities	3 months to 1 year	4,206	—	(3)	4,203
U.S. Treasury securities	3 months to 1 year	2,941	1	—	2,942
		<u>\$ 60,451</u>	<u>\$ 18</u>	<u>\$ (3)</u>	<u>\$ 60,466</u>

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As of December 31, 2023, the Company had the following investments in available-for-sale debt securities (in thousands):

	<u>Remaining contractual maturity</u>	<u>Amortized cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Aggregate estimated fair value</u>
<b>Cash equivalents:</b>					
Corporate debt securities	Less than 3 months	\$ 1,601	\$ —	\$ (1)	\$ 1,600
		<u>\$ 1,601</u>	<u>\$ —</u>	<u>\$ (1)</u>	<u>\$ 1,600</u>
<b>Available-for-sale debt securities:</b>					
Corporate debt securities	3 months to 1 year	2,940	7	—	2,947
		<u>\$ 2,940</u>	<u>\$ 7</u>	<u>\$ —</u>	<u>\$ 2,947</u>

Management determines the appropriate classification of its investments in available-for-sale debt securities at the time of purchase and reevaluates such designation as of each reporting date. The securities are classified as current or non-current based on the maturity dates and management's intentions.

At December 31, 2024, the Company has classified all of its available-for-sale debt securities as current assets on the accompanying Consolidated Balance Sheets based on the highly-liquid nature of these investment securities and because these investment securities are considered available for use in current operations.

The investments in available-for-sale debt securities are measured at fair value at each reporting date. Unrealized gains and losses are excluded from earnings and are reported as a component of Other comprehensive (loss) income, net of tax. Realized gains and losses are included in Other income (expense), net. Interest income and amortization of premiums and discounts at acquisition are included in Interest income. In the year ended December 31, 2024, 2023 and 2022 proceeds from the maturity or redemption of available-for-sale debt securities were \$44,057,000, \$210,983,000 and \$166,994,000, respectively. There were realized gains of \$nil, \$198,000 and \$nil recognized on settlement of available-for-sale debt securities during the years ended December 31, 2024, 2023 and 2022 respectively. The Company reclassified the gains and losses out of accumulated other comprehensive loss during the same periods.

At each reporting date, the Company assesses whether each individual investment is impaired, which occurs if the fair value is less than the amortized cost, adjusted for amortization of premiums and discounts at acquisition. If the investment is impaired, the impairment is assessed to determine if the impairment has resulted from a credit loss or other factors. Impairments judged to be due to credit losses are included in other (expense) income, net through an allowance for credit losses when they are identified.

The aggregate fair value (in thousands) and number of securities held by the Company (including those classified as cash equivalents) in an unrealized loss position as of December 31, 2024 and 2023 are as follows (in thousands):



	December 31, 2024			December 31, 2023		
	Fair market value of investments in an unrealized loss position	Number of investments in an unrealized loss position	Unrealized losses	Fair market value of investments in an unrealized loss position	Number of investments in an unrealized loss position	Unrealized losses
<b>Marketable securities in a continuous loss position for less than 12 months:</b>						
Corporate debt securities	\$ 4,679	2	\$ (3)	\$ 1,600	1	\$ (1)
	<b>\$ 4,679</b>	<b>2</b>	<b>\$ (3)</b>	<b>\$ 1,600</b>	<b>1</b>	<b>\$ (1)</b>

As of December 31, 2024 and 2023, no allowance for expected credit losses has been recognized in relation to securities in an unrealized loss position. This is because the unrealized losses are not severe, do not represent a significant proportion of the total fair market value of the investments and all securities have an investment-grade credit rating. Furthermore, the Company does not intend to sell the debt securities in unrealized loss positions, and it is unlikely that the Company will be required to sell the securities before the recovery of the amortized cost.

The cost of securities sold is based on the specific-identification method. Interest on debt securities is included in interest income.

Our investments in available-for-sale debt securities are subject to credit risk. The Company's investment policy limits investments to certain types of instruments, such as money market instruments and corporate debt securities, places restrictions on maturities and concentration by type and issuer and specifies the minimum credit ratings for all investments and the average credit quality of the portfolio.

**(i) Accounts receivable**

Accounts receivable include amounts billed to customers and accrued receivables where only the passage of time is required before payment of amounts due.

Management analyses current and past due accounts and determines if an allowance for credit losses is required based on collection experience, credit worthiness of customers and other relevant information. As of December 31, 2024 and 2023, no allowance for expected credit losses is recognized on the basis that the possibility of credit losses arising on its receivables is considered to be remote. The process of estimating credit losses involves assumptions and judgments and the ultimate amounts of uncollectible accounts receivable could be in excess of the amounts provided.

**(j) Clinical materials**

Clinical materials for use in research and development with alternative future use are capitalized as either other current assets or other non-current assets, depending on the timing of their expected consumption. The Company assesses whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable.

**(k) Property, plant and equipment**

Property, plant and equipment is stated at cost, less any impairment losses, less accumulated depreciation.

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Depreciation is computed using the straight-line method over the estimated useful lives of the related assets. The following table provides the range of estimated useful lives used for each asset type:

Computer equipment	3 to 5 years
Laboratory equipment	5 years
Office equipment	5 years
Leasehold improvements	the expected duration of the lease

Assets under construction are not depreciated until the asset is available and ready for its intended use.

The Company assesses property, plant and equipment for impairment whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable.

**(l) Intangibles**

Intangibles primarily include acquired software licenses and third-party software in development, which are recorded at cost and amortized over the estimated useful lives of approximately three years. Intangibles also comprises in-licensed technology which is recognized over the estimated period that the Company expects to utilize the technology.

Intangibles are assessed for impairment whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable.

**(m) Leases**

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to use, or control the use of, identified property, plant, or equipment for a period of time in exchange for consideration. Leases may be classified as finance leases or operating leases. All the Company's leases are classified as operating leases. Operating lease right-of-use (ROU) assets and operating lease liabilities recognized in the Consolidated Balance Sheet represent the right to use an underlying asset for the lease term and an obligation to make lease payments arising from the lease respectively.

Operating lease ROU assets and operating lease liabilities are recognized at the lease commencement date based on the present value of minimum lease payments over the lease term. Since the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rates (the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term for an amount equal to the lease payments in a similar economic environment) based on the information available at commencement date in determining the discount rate used to calculate the present value of lease payments. The incremental borrowing rates are determined using information on indicative borrowing rates that would be available to the Company based on the value, currency and borrowing term provided by financial institutions, adjusted for company and market specific factors. The lease term is based on the non-cancellable period in the lease contract, and options to extend the lease are included when it is reasonably certain that the Company will exercise that option. Any termination fees are included in the calculation of the ROU asset and lease liability when it is assumed that the lease will be terminated.

The Company accounts for lease components (e.g. fixed payments including rent and termination costs) separately from non-lease components (e.g. common-area maintenance costs and service charges based on utilization) which are recognized over the period in which the obligation occurs.

At each reporting date, the operating lease liabilities are increased by interest and reduced by repayments made under the lease agreements.

The ROU asset is subsequently measured for an operating lease at the amount of the remeasured lease liability (i.e. the present value of the remaining lease payments), adjusted for the remaining balance of any lease incentives

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received, any cumulative prepaid or accrued rent if the lease payments are uneven throughout the lease term, and any unamortized initial direct costs.

The Company has operating leases in relation to property for office and research facilities. All of the leases have termination options, and it is assumed that the initial termination options for the buildings will be activated for most of these. The maximum lease term without activation of termination options is to 2041.

In May 2017, the Company entered into an agreement for the lease of a building at Milton Park, Oxfordshire, United Kingdom and in February 2018 the Company entered into the lease for that facility. The term of the lease expires on October 23, 2041, with termination options exercisable by the Company in October 2031 and October 2036.

In September 2015, the Company entered into an agreement for a 25-year lease, with early termination options, for a research and development facility in Oxfordshire, United Kingdom. In October 2016, the Company entered into the lease for that facility following the completion of construction. The term of the lease expires on October 23, 2041, with termination options exercisable by the Company in October 2031 and October 2036.

In July 2015, the Company entered into a 15-year lease agreement, with an early termination option at 123 months, for offices and research facilities in Philadelphia, United States. The lease commenced upon completion of construction in October 2016.

In August 2021, the Company entered into a two-year lease agreement for the lease of a building at Milton Park, Oxfordshire, United Kingdom with the term of the lease expiring on August 12, 2023. The lease contained termination options exercisable by the Company on a minimum of four months prior notice. During January 2023, the Company served notice to terminate the lease effective on May 31, 2023.

On June 1, 2023, as part of the acquisition of TCR<sup>2</sup>, the Company became the lessee of three office, manufacturing and research facilities in Cambridge, Massachusetts. The term of each of these leases expires on January 15, 2024, September 30, 2024, and January 31, 2026, respectively.

The Company has elected not to recognize an ROU asset and lease liability for short-term leases. A short-term lease is a lease with a lease term of 12 months or less and which does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Operating lease costs are recognized on a straight-line basis over the lease term, and they are categorized within Research and development and Selling, general and administrative expenses in the Consolidated Statement of Operations. The operating lease cash flows are categorized under Net cash used in operating activities in the Consolidated Statement of Cash Flows.

**(n) Segmental reporting**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company's chief operating decision maker (the "CODM"), its Chief Executive Officer and the senior leadership team (comprising the Executive Team members and three senior vice presidents), manages the Company's operations on an integrated basis for the purposes of allocating resources. When evaluating the Company's financial performance, the CODM reviews total revenues, total expenses and expenses by function and the CODM makes decisions using this information on a global basis. Accordingly, the Company has determined that it operates in one operating segment.

**(o) Revenue**

Revenue is recognized so as to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

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Step 1: Identify the contract(s) with a customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract.

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The application of these steps to our collaboration agreements is discussed in further detail by agreement in Note 3.

**Development revenue – collaboration agreements**

*Variable consideration*

The Company determines the variable consideration to be included in the transaction price by estimating the most likely amount that will be received and then applies a constraint to reduce the consideration to the amount which is probable of being received. The determination of whether a milestone is probable includes consideration of the following factors:

- whether achievement of a development milestone is highly susceptible to factors outside the entity's influence, such as milestones involving the judgment or actions of third parties, including regulatory bodies or the customer;
- whether the uncertainty about the achievement of the milestone is not expected to be resolved for a long period of time;
- whether the Company can reasonably predict that a milestone will be achieved based on previous experience; and
- the complexity and inherent uncertainty underlying the achievement of the milestone.

*Percentage of completion*

The determination of the percentage of completion requires the Company to estimate the costs-to-complete the project or, for the GSK Termination and Transfer Agreement only, the total estimated periods of active patient enrollment over the estimated duration of the trial.

The Company makes a detailed estimate of the costs-to-complete, estimated periods of active patient enrollment and estimated trial duration, which is re-assessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate will be adjusted and the revenue will be recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate would be recognized as an adjustment to revenue in the period in which the change in estimate occurs.

*Contract assets and liabilities*

The Company recognizes a contract asset, when the value of satisfied (or part satisfied) performance obligations is in excess of the payment due to the Company, and deferred revenue (contract liability) when the amount of unconditional consideration is in excess of the value of satisfied (or part satisfied) performance obligations. Once a right to receive consideration is unconditional, that amount is presented as a receivable.

Changes in deferred revenue typically arise due to:

- adjustments arising from a change in the estimate of the cost to complete the project, which results in a cumulative catch-up adjustment to revenue that affects the corresponding contract asset or deferred revenue;
- a change in the estimate of the transaction price due to changes in the assessment of whether variable consideration is constrained because it is not considered probable of being received;
- the recognition of revenue arising from deferred revenue; and
- the reclassification of amounts to receivables when a right to consideration becomes unconditional.

A change in the estimate of variable consideration constrained (for example, if a development milestone becomes probable of being received) could result in a significant change in the revenue recognized and deferred revenue.

### **Product revenue**

The Company generates revenue from sales of its commercially approved T-cell therapy. As of December 31, 2024, the Company's only commercially approved product was TECELRA® ("TECELRA"), which was approved by the FDA on August 1, 2024. The Company's customers for TECELRA are Authorized Treatment Centers ("ATCs").

Revenue from product sales is recognized at the point in time that the customer obtains control of the product, which is typically upon delivery of the product to the ATC. Revenue from product sales is recognized net of estimates of variable consideration, which includes chargebacks, rebates, returns, discounts and co-pay. This variable consideration is estimated using the expected value method, based on Management's best estimate of the amount that the Company will be entitled to. The actual amounts of consideration received may differ from our estimates. If actual consideration in the future differs from the Company's estimates, these estimates will be adjusted, which would affect net product revenue in the period such variances are adjusted.

The components of variable consideration can differ from sale to sale and may include the following:

#### *Chargebacks*

The Company is required to provide product to certain customers at a reduced price. The Company estimates chargebacks based on the number of sales made through qualifying programs. Chargebacks are recognized as a reduction to revenue when a product sale is recognized, with a corresponding reduction to the receivable recognized in relation to the sale.

#### *Government rebates*

The Company is subject to various governmental rebates in the U.S. such as Medicaid. The Company estimates chargebacks based on the number of sales made to customers through qualifying programs and historical experience. The Company includes estimates for rebates payable as a reduction to revenue when a product sale is recognized, with a corresponding liability recognized within Accrued commercial expenses and provisions.

#### *Product returns*

Customers have limited rights to return a product, such as if the product is unable to be administered to the patient, or is defective or damaged. The Company estimates the amount of product sales that may be returned by customers and records this as a reduction to revenue when a product sale is recognized. The Company bases its current estimate of product returns on return rates for similar products in the market adjusted for factors specific to TECELRA; once a sufficient history of sales has been developed, the estimate will be based on historical experience, adjusted for other known factors that may influence returns.

*Other deductions*

The Company may be subject to, or provide, other incentives or rebates such as co-payment assistance that will reduce the amount of revenue to which it is ultimately entitled. The Company will estimate such deductions based on the patient mix and historical experience. The estimate is recorded as a reduction to revenue when a product sale is recognized.

**(p) Inventory**

The Company commences capitalization of inventories once regulatory approval of the product to which the inventories relate is received or considered probable. Until this date, the Company expenses all such costs as incurred as research and development expenses. The Company capitalizes material costs, labor and applicable overheads that are incurred in the production of its commercial product.

The Company values inventory at the lower of cost or net realizable value on a first-in-first-out basis. The Company reviews the recoverability of inventory each reporting period to determine any changes to net realizable value arising from excess, slow-moving or obsolete inventory. If net realizable value is lower than cost, the inventory will be written down to net realizable value and an impairment charge will be recognized in cost of goods sold.

Inventory that can be used for either clinical or commercial purposes is classified initially as inventory. Inventory that is subsequently designated to be used in clinical trials and is no longer available for use in commercial products is expensed as research and development expenditure from the point that it becomes exclusively for clinical use, unless it has an alternative future use in which case it is classified as Clinical materials.

**(q) Research and development expenditures**

Research and development expenditures are expensed as incurred.

Expenses related to clinical trials are recognized as services are received. Nonrefundable advance payments for services are deferred and recognized in the Consolidated Statement of Operations as the services are rendered. This determination is based on an estimate of the services received and there may be instances when the payments to vendors exceed the level of services provided resulting in a prepayment of the clinical expense. If the actual timing of the performance of services varies from our estimate, the accrual or prepaid expense is adjusted accordingly.

Upfront and milestone payments to third parties for in-licensed products or technology which has not yet received regulatory approval and which does not have alternative future use in R&D projects or otherwise are expensed as incurred. The Company recognized an expense in relation to in-process R&D of \$52,000 and \$2,316,000 in the years ended December 31, 2024 and 2022, respectively, and a credit of \$1,840,000 in the year ended December 31, 2023.

Milestone payments made to third parties either on or subsequent to regulatory approval are capitalized as an intangible asset and amortized over the remaining useful life of the product.

Research and development expenditure is presented net of R&D tax and expenditure credits from the U.K. government, which are recognized over the period necessary to match the reimbursement with the related costs when it is probable that the Company has complied with any conditions attached and will receive the reimbursement. As a company that carries out extensive research and development activities, Adaptimmune Limited is able to surrender the trading losses that arise from its qualifying research and development activities for a payable tax credit. Reimbursable R&D tax and expenditure credits were \$11,467,000, \$15,542,000, and \$30,226,000 in the years ended December 31, 2024, 2023 and 2022, respectively.

**(r) Share-based compensation**

The Company awards certain employees options over the ordinary shares of the parent company. The cost of share-based awards issued to employees are measured at the grant-date fair value of the award and recognized as an

expense over the requisite service period. The fair value of the options is determined using the Black-Scholes option-pricing model. Share options with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company has elected to account for forfeitures of stock options when they occur by reversing compensation cost previously recognized, in the period the award is forfeited, for an award that is forfeited before completion of the requisite service period.

**(s) Retirement benefits**

The Company operates defined contribution pension schemes for its directors and employees. The contributions to this scheme are expensed to the Consolidated Statement of Operations as they fall due. The pension contributions for the years ended December 31, 2024, 2023, and 2022 were \$3,085,000, \$2,628,000 and \$2,810,000, respectively.

**(t) Interest income**

Interest income arises on cash, cash equivalents and available-for-sale debt securities and is net of amortization (accretion) of the premium (discount) on purchase of the debt securities of (\$1,407,000), (\$1,986,000), and \$2,525,000 in the years ended December 31, 2024, 2023 and 2022, respectively.

**(u) Income taxes**

Income taxes for the period comprise current and deferred tax. Income tax is recognized in the Consolidated Statement of Operations except to the extent that it relates to items occurring during the year recognized either in other comprehensive income or directly in equity, in which case it is recognized in other comprehensive income or equity. We release stranded tax effects from accumulated other comprehensive income using the portfolio approach.

Current tax is the expected tax payable or receivable on the taxable income or loss for the current or prior periods using tax rates enacted at the balance sheet date.

Deferred tax is accounted for using the asset and liability method that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amount and the tax bases of assets and liabilities at the applicable tax rates and for operating loss and tax credit carryforwards. A valuation allowance is provided to reduce deferred tax assets to the amount that is more likely than not to be realized. The Company evaluates the realizability of its deferred tax assets and adjusts the amount of the valuation allowance, if necessary. The factors used to assess the likelihood of realization include the Company's forecast of income, carryback availability, reversing taxable temporary differences and available tax-planning strategies that could be implemented to realize the deferred tax assets.

Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. Income tax positions that previously failed to meet the more-likely-than-not threshold are recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not threshold are derecognized in the first subsequent financial reporting period in which that threshold is no longer met. Recognized income tax positions are measured at the largest amount that is greater than 50 percent likely of being realized. We recognize potential accrued interest and penalties related to income taxes within the Consolidated Statement of Operations as income tax expense.

**(v) Loss per share**

Basic loss per share is determined by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is determined by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period, adjusted for the dilutive effect of all potential ordinary shares that were outstanding during the period. Potentially dilutive shares are excluded when the effect would be to increase diluted earnings per share or reduce diluted loss per share.

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The following table reconciles the numerator and denominator in the basic and diluted loss per share computation (in thousands):

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
<b>Numerator for basic and diluted loss per share</b>			
Net loss	\$ (70,814)	\$ (113,871)	\$ (165,456)
<b>Net loss attributable to shareholders used for basic and diluted EPS calculation</b>	<b>\$ (70,814)</b>	<b>\$ (113,871)</b>	<b>\$ (165,456)</b>
<b>Denominator for basic and diluted loss per share</b>			
Weighted average number of shares used to calculate basic and diluted loss per share	1,513,810,852	1,206,440,978	967,242,403

The effects of the following potentially dilutive equity instruments have been excluded from the diluted loss per share calculation because they would have an antidilutive effect on the loss per share for the period:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Weighted average number of share options	252,267,387	185,994,528	155,673,264

From January 1, 2025 through to March 24, 2025 the Company granted 24,711,600 options over ordinary shares with an exercise price determined by reference to the market value of an ADS at the closing rate on the last business day prior to the date of grant, and 24,944,376 options over ordinary shares with an exercise price equal to the nominal value of the ordinary shares (£0.001 per share). These grants have not been included in the figures above.

**(w) Restructuring costs**

Restructuring costs are comprised of amounts payable to employees and other parties because of redundancy related to restructuring programs. The Company classifies redundancy payments as either, contractual termination benefits if they relate to an ongoing benefit arrangement, including terms of employment contracts or termination benefits that arise from employment law in the relevant jurisdiction, or, one-time employee termination benefits if the benefits are not related to an ongoing benefit arrangement or represent a one-time enhancement to an ongoing benefit arrangement.

A liability for contractual termination benefits is recognized when it is probable that employees will be entitled to benefits and the amount can be reasonably estimated.

A liability for one-time employee termination benefits is recognized from the communication date. If employees are not required to render service until they are terminated or will not be retained to render service beyond the minimum retention period in order to receive the termination benefits, a liability for one-time employee termination benefits is recognized at the communication date. If employees are required to render services beyond the minimum retention period in order to receive the termination benefits, a liability is measured initially at the communication date based on the fair value of the liability as of the termination date and is recognized ratably over the required service period.

Restructuring costs are recognized within selling, general and administrative expenses with the corresponding liability recognized in current or non-current liabilities depending on the expected timing of payments.



**(x) New accounting pronouncements**

*Adopted in the year ended December 31, 2024*

*Improvements to Reportable Segment Disclosures*

In November 2023, the FASB issued ASU 2023-07 – Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which improves segment disclosure requirements, primarily through enhanced disclosure requirements for significant segment expenses. The improved disclosure requirements apply to all public entities that are required to report segment information, including those with only one reportable segment. The Company adopted the guidance in the fiscal year beginning January 1, 2024. There was no impact on the Company’s reportable segments identified and additional required disclosures have been included in Note 14.

*Codification Improvements*

In March 2024, the FASB issued ASU 2024-02 - Codification Improvements—Amendments to remove References to the Concepts Statements, which contains amendments to the Codification that remove references to various FASB Concepts Statements. The amendments apply to all reporting entities within the scope of the affected accounting guidance and are effective for public business entities for fiscal years beginning after December 15, 2024, with early adoption permitted for all entities. The Company adopted the guidance in the fiscal year beginning January 1, 2024. There was no impact on the Company’s financial statements.

*To be adopted in future periods*

*Disaggregation of Income Statement Expenses*

In November 2024, the FASB issued ASU 2024-03 Disaggregation of Income Statement Expense, which improves disclosure around the nature of expenses included in the income statement. The improvements require entities to disaggregate and disclose the amounts of certain types of expenses included in certain expense captions. For public business entities, the guidance is effective for annual periods beginning after December 15, 2026, with early adoption permitted. The Company intends to adopt the guidance in the fiscal year beginning January 1, 2027. The Company is currently evaluating the impact of the guidance on its Consolidated financial statements.

*Improvements to Income Tax Disclosures*

In December 2023, the FASB issued ASU 2023-09 – Income Taxes (Topic 740) – Improvements to Income Tax Disclosures, which improves income tax disclosures primarily relating to the rate reconciliation and income taxes paid information. This includes a tabular reconciliation using both percentages and reporting currency amounts, covering various tax and reconciling items, and disaggregated summaries of income taxes paid during the period. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company intends to adopt the guidance in the fiscal year beginning January 1, 2025. The Company is currently evaluating the impact of the guidance on its Consolidated financial statements.

**(y) Business combinations**

The Company determines whether a transaction or other event is a business combination by determining whether the assets acquired and liabilities assumed constitute a business. Business combinations are accounted for by applying the acquisition method as set out by ASC 805 *Business combinations*. The acquisition method of accounting requires the acquirer to recognize and measure all identifiable assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at their acquisition-date fair values, with certain exceptions for specific items.

For leases acquired in a business combination in which the acquiree is a lessee, the acquirer shall measure the lease liability at the present value of the remaining lease payments, as if the acquired lease were a new lease of the

acquirer at the acquisition date. The right-of-use asset shall be measured at the same amount as the lease liability, adjusted to reflect favorable or unfavorable terms of the lease when compared with market terms. For leases in which the acquired entity is a lessee, the Company has elected not to recognize assets or liabilities at the acquisition date for leases that, at the acquisition date, have a remaining lease term of 12 months or less.

Goodwill is measured as the excess of the consideration transferred in the business combination over the net acquisition date amounts of the identifiable assets acquired and the liabilities assumed. If instead the net acquisition date amounts of the identifiable assets acquired and the liabilities assumed exceeds the consideration transferred, a gain on bargain purchase is recognized in the Consolidated Statement of Operations. The consideration transferred in a business combination is measured as the sum of the fair values of the assets transferred by the acquiring entity, the liabilities incurred by the acquiring entity to former owners of the acquired entity, and the equity interests issued by the acquiring entity.

The results of operations of businesses acquired by the Company are included in the Company's Consolidated Statement of Operations as of the respective acquisition date.

Where the acquiring entity exchanges its share-based payment awards for awards held by grantees of the acquiree, such exchanges are treated as a modification of share-based payment awards and are referred to as replacement awards. The replacement awards are measured as of the acquisition date and the portion of the fair-value-based measure of the replacement award that is attributable to pre-combination vesting is considered part of the consideration transferred. For awards with service-based vesting conditions only, the amount attributable to pre-combination vesting is the fair-value-based measure of the acquiree award multiplied by the ratio of the employee's pre-combination service period to the greater of the total service period of the original service period of the acquiree award.

Acquisition-related costs, including advisory, legal and other professional fees and administrative fees are expensed as incurred except for the costs of issuing equity securities, which are recognized as a reduction to the amounts recognized in the Statement of Changes in Equity for the respective equity issuance.

**(z) Impairment of long-lived assets**

Long-lived assets, or asset groups, are tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. An impairment loss is recognized only if the carrying amount of an asset or asset group is not recoverable and exceeds its fair value. The carrying amount of an asset or asset group is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset or asset group. If the carrying amount is not recoverable, an impairment loss is recognized based on the amount by which the carrying value of the asset or asset group exceeds its fair value. The adjusted carrying amount of the asset after the impairment loss is recognized becomes its new cost basis.

The Company uses a combination of a market-based and income-based present value approaches to determining the fair value of assets or asset groups.

**(aa) Borrowings**

The Company recognizes borrowings comprised solely of contractual payments on fixed or determinable dates that are issued solely for cash equal to their face value, at face value with the difference between the face amount and proceeds received upon issuance shown as either a discount or premium.

These notes are subsequently measured using the Interest Method, with the total interest being measured as the difference between the actual amount of cash received by the Company and the total amount agreed to be repaid. The interest charge in a given period is based on the effective interest rate, which is the rate implicit in the note based on the contractual cash flows. The discount or premium on the note is amortized as interest expense over the life of the note so as to produce a constant rate of interest.

**(ab) Provisions**

The Company recognizes an estimated loss from a loss contingency when both of the following conditions are met:

- a. It is probable that an asset has been impaired or liability incurred at the date of the financial statements,
- b. The amount of the loss can be reasonably estimated.

Where a loss contingency meets the recognition criteria, a liability and corresponding charge to the Statement of Operations is recognized based on the estimated loss. Where there is a range of potential losses, if any amount within the range is better than any other, then that amount shall be accrued. If no amount within the range is better than any other then the minimum amount shall be accrued.

If a loss contingency does not meet the recognition criteria but if a loss is considered reasonably possible then the loss contingency will be disclosed but not recognized as a liability. If the possibility of a loss is considered to be remote, then no loss contingency is recognized or disclosed.

**Note 3 — Revenue**

The Company generates Product revenue from sales of TECELRA.

The Company generates development revenue from collaboration agreements with customers. The Company had three development revenue-generating contracts with customers in the years ended December 31, 2024 and 2023, respectively: a collaboration agreement with Astellas that was terminated as of March 6, 2023, a collaboration and license agreement with Galapagos executed on May 30, 2024, a strategic collaboration and license agreement with Genentech that was terminated effective September 23, 2024 and a termination and transfer agreement with GSK that was entered into on April 6, 2023. The original collaboration and license agreement with GSK was terminated in 2022.

Revenue comprises the following categories (in thousands):

	Year ended December 31,		
	2024	2023	2022
Product revenue, net	\$ 1,236	\$ —	\$ —
Development revenue	176,796	60,281	27,148
	<u>\$ 178,032</u>	<u>\$ 60,281</u>	<u>\$ 27,148</u>

All deferred revenue at December 31, 2024, 2023 and 2022 relates to development revenue. Deferred revenue decreased by \$69,922,000 from \$178,033,000 at December 31, 2023 to \$108,111,000 at December 31, 2024 primarily due to \$163,353,000 of revenue recognized in the year that was included in opening deferred revenue and a \$1,600,000 decrease caused by the change in the exchange rate between pounds sterling and the U.S. dollar from £1.00 to \$1.27 at December 31, 2023 to £1.00 to \$1.25 at December 31, 2024. This was offset by payments of \$85,000,000, \$876,000 and \$9,673,000 from Galapagos, Genentech and GSK, respectively.

Deferred revenue decreased by \$6,379,000 from \$184,412,000 at December 31, 2022 to \$178,033,000 at December 31, 2023 primarily due to \$59,072,000 of revenue recognized in the year that was included in opening deferred revenue. This was offset by a \$7,174,000 increase caused by the change in the exchange rate between pounds sterling and the U.S. dollar from £1.00 to \$1.21 at December 31, 2022 to £1.00 to \$1.27 at December 31, 2023, by additional payments of \$15,000,000 received under the Genentech Collaboration and License Agreement in November 2023, and by payments of \$9,613,000, \$3,727,000 and \$15,226,000 from GSK in the second, third and fourth quarters of 2023, respectively.

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The aggregate amount of the transaction price that is allocated to performance obligations that are unsatisfied or partially satisfied under the agreements as of December 31, 2024, was \$124,393,000.

*The Galapagos Collaboration and Exclusive License Agreement*

On May 30, 2024, the Company entered into the Galapagos Collaboration Agreement, a clinical collaboration agreement with Galapagos. The Galapagos Collaboration Agreement includes an option for Galapagos to exclusively license the TCR T-cell therapy candidate uza-cel, manufactured on Galapagos' decentralized manufacturing platform, in head and neck cancer and potential future solid tumor indications. Under the Galapagos Collaboration Agreement, the Company will conduct a clinical proof-of-concept trial (the "POC Trial") to evaluate the safety and efficacy of uza-cel produced utilizing Galapagos' decentralized manufacturing platform for patients with head and neck cancer.

Under the terms of the agreement, the Company will receive initial payments of \$100 million, comprising \$70 million upfront and \$30 million of research and development funding of which \$15 million is due upfront and \$15 million is due once the first patient is infused in the POC Trial. In addition, there are option exercise fees of up to \$100 million (the amount depending on the number of indications in relation to which the option is exercised), additional development and sales milestone payments of up to a maximum of \$465 million, plus tiered royalties on net sales. The \$70 million upfront payment and \$15 million of upfront research and development funding was received by the Company in June 2024.

The Company determined that Galapagos is a customer and has accounted for the agreement under ASC 606 *Revenue from Contracts with Customers*. The Company has identified a performance obligation relating to the various activities required to complete the POC trial and a material right associated with the exclusive license option.

The aggregate transaction price at inception of the Galapagos Collaboration Agreement was \$100,000,000 comprising the \$70,000,000 upfront payment and the \$30,000,000 research and development funding. The fees for the exclusive license option exercise and development milestone payments are not considered probable as of December 31, 2024 and have not been included in the transaction price. The sales milestones and royalties for future sales of therapies have not been included within the transaction price as of December 31, 2024 because they are sales-based and will be recognized if/when the subsequent sales occur.

The aggregate transaction price is allocated to the performance obligations depending on the relative standalone selling price of the performance obligations. In determining the best estimate of the relative standalone selling price, the Company considered the internal pricing objectives it used in negotiating the contract, together with internal data regarding the expected costs and a standard margin on those costs, for completing the POC Trial. The residual approach was used to value the material right associated with the exclusive license option as the Company has not previously sold uza-cel on a standalone basis and has not established a price for uza-cel.

The Company expects to satisfy the POC Trial obligation over the period that the trial is completed, based on an estimate of the percentage of completion of the trial determined based on the costs incurred on the trial as a percentage of the total expected costs. The revenue allocated to the material right associated with the exclusive license option will be recognized from the point that the option is either exercised and control of the license has passed to Galapagos or the option lapses.

The amount of the transaction price that is allocated to performance obligations that are unsatisfied or partially satisfied under the agreement as of December 31, 2024 was \$99,487,000, of which \$43,887,000 is allocated to the POC Trial performance obligation and \$55,600,000 is allocated to the material right for the exclusive option.

*The Genentech Collaboration and License Agreement*

On September 3, 2021, the Company entered into a Strategic Collaboration and License Agreement with Genentech, Inc. and F. Hoffman-La Roche Ltd, which became effective on October 19, 2021 upon expiry or termination of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

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Under the Agreement, Genentech and Adaptimmune (each, a “party” and together, the “parties”) would collaborate to develop two types of allogeneic T-cell therapies: (i) “off-the-shelf”  $\alpha\beta$  T-cell therapies directed to initial collaboration targets, with Genentech having the right to designate additional collaboration targets, up to five collaboration targets in total, and (ii) personalized therapies utilizing  $\alpha\beta$  T-cell receptors (TCRs) isolated from a patient, with such therapies being administered to the same patient.

Under the terms of the Agreement, Adaptimmune would receive \$150 million as an upfront payment, which was received in the fourth quarter of 2021. Adaptimmune may also receive:

- \$150 million in additional payments spread over a period of 5 years from the effective date of the Agreement, unless the agreement is earlier terminated, of which milestones of \$20 million and \$15 million were received in the fourth quarters of 2022 and 2023, respectively;
- Research milestones of up to \$50 million;
- Development milestones of up to \$100 million in relation to the development of “off-the-shelf” T-cell therapies per collaboration target (unless Adaptimmune exercises its right to opt-in to receive a profit share) and up to \$200 million in relation to the development of personalized T-cell therapies;
- Commercialization milestones of up to \$1.1 billion for “off-the-shelf” T-cell therapies (unless Adaptimmune exercises its right to opt-in to receive a profit share and assuming “off-the-shelf” T-cell therapies are developed to 5 targets) and for personalized T-cell therapies; and
- Net sales milestones of up to \$1.5 billion for “off-the-shelf” T-cell therapies (unless Adaptimmune exercises its right to opt-in to receive a profit share and assuming “off-the-shelf” T-cell therapies are developed to 5 targets) and for personalized T-cell therapies.

In addition, Adaptimmune would receive tiered royalties on net sales in the mid-single to low-double digits. Collaboration target designation fees apply if Genentech exercises its right to designate additional “off-the-shelf” collaboration targets up to a maximum of 5 targets.

The Company assessed the agreement under the provisions of ASC 606, Revenue from Contracts with Customers and ASC 808, Collaborative Arrangements. The Company determined that Genentech is a customer and has applied the provisions of ASC 606 to the contract and related performance obligations. The Company identified the following performance obligations under the agreement: (i) research services and rights granted under the licenses for each of the initial ‘off-the-shelf’ collaboration targets, (ii) research services and rights granted under the licenses for the personalized therapies, (iii) material rights relating to the option to designate each of the additional ‘off-the-shelf’ collaboration targets and (iv) material rights relating to the two options to extend the research term. The Company began recognizing revenue for the performance obligations relating to the initial ‘off-the-shelf’ collaboration targets and the personalized therapies in 2021.

The Company originally expected to satisfy the performance obligations relating to the initial ‘off-the-shelf’ collaboration targets and the personalized therapies as development progressed and recognized revenue based on an estimate of the percentage of completion of the project determined based on the costs incurred on the project as a percentage of the total expected costs. The Company expected to satisfy the performance obligations relating to the material rights to designate additional ‘off-the-shelf’ collaboration targets from the point that the options would have been exercised and then as development progressed, in line with the initial ‘off-the-shelf’ collaboration targets, or at the point in time that the rights expired. The Company expected to satisfy the performance obligations relating to the material rights to extend the research term from the point that the options would have been exercised and then over the period of the extension, or at the point in time that the rights expired.

On April 12, 2024 the Company announced the termination of the Genentech Collaboration Agreement, entered into by Adaptimmune Limited, a wholly-owned subsidiary of the Company, in relation to the research, development and commercialization of cancer targeted allogeneic T-cell therapies which was originally scheduled to be effective from October 7, 2024. The termination was accounted for as a contract modification on a cumulative catch-up basis. The termination did not change the nature of the performance obligations identified but resulted in a reduction in the transaction price as the additional payments and variable consideration that would have been due in periods after October 7, 2024 will now never be received.

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The aggregate remaining transaction price that had not yet been recognized as revenue as of the date of the termination was \$146,301,000 which included the remaining deferred revenue that had not been recognized as revenue as of the date of the modification and the variable consideration to be billed under the collaboration until the effective date of the termination that is still considered probable. The termination resulted in a cumulative catch-up adjustment to revenue at the date of the termination of \$101,348,000 and a further \$20,741,000 of revenue recognized in the second quarter of 2024.

On September 23, 2024, the Adaptimmune Limited entered into a Mutual Release and Resolution Agreement (the “Mutual Release Agreement”) with Genentech. This agreement, among other things, resolved and released each party from any and all past, present and future disputes, claims, demands and causes of action, whether known or unknown, related to the Genentech Collaboration Agreement in any way. Under the terms of the Mutual Release Agreement, Genentech will pay the Company \$12.5 million upon which the Genentech Collaboration Agreement will be terminated. The \$12.5 million was received in October 2024. The Agreement was effective immediately as of September 23, 2024.

The Mutual Release Agreement resulted in all remaining performance obligations being fully satisfied and the remaining deferred revenue of \$25,298,000 and the additional payment of \$12,500,000 were both recognized as total revenue of \$37,798,000 in the third quarter of 2024.

### *The Astellas Collaboration Agreement*

The Company and Universal Cells mutually agreed to terminate the Astellas Collaboration Agreement as of March 6, 2023 (the “Termination Date”). In connection with the termination, all licenses and sublicenses granted to either party pursuant to the Collaboration Agreement ceased as of the Termination Date. There were no termination penalties in connection with the termination; however the Company is still entitled to receive reimbursement for research and development work performed up to and including a period of 30 days after the Termination Date.

The Company originally satisfied the performance obligations relating to the three co-development targets as development progresses and recognized revenue based on an estimate of the percentage of completion of the project determined based on the costs incurred on the project as a percentage of the total expected costs. The Company originally determined that the performance obligations relating to the two independent Astellas targets would be recognized at a point-in-time, upon commencement of the licenses in the event of nomination of the target, since they were right-to-use licenses.

The termination was accounted for as a contract modification on a cumulative catch-up basis. No performance obligations were identified as a result of the modification as there were no further goods or services to be provided by the Company and the modification resulted in the remaining unsatisfied and partially satisfied performance obligations under the collaboration becoming fully satisfied. The aggregate transaction price of the contract modification was \$42,365,000 which included the remaining deferred income that had not been recognized as revenue as of the date of the modification and variable consideration from the remaining reimbursement income to be billed under the collaboration at the end of the 30 day period after the Effective Date. The transaction price of the modification was recognized in full in March 2023 and there is no remaining transaction price allocated to performance obligations that are unsatisfied or partially satisfied under, no remaining deferred income relating to, the agreement as of December 31, 2024.

### *The GSK Collaboration and License Agreement*

The GSK Collaboration and License Agreement consisted of multiple performance obligations, including the development of a third target, which was the only performance obligation for which revenue was recognized in 2022.

The collaboration was terminated by GSK in October 2022 (effective December 23, 2022). A further amendment to the collaboration agreement was entered into on December 19, 2022 for the deletion of certain provisions relating to GSK’s post termination manufacturing and supply obligations and payment of £5,000,000 by GSK to Adaptimmune. The aggregate transaction price of the contract modification was \$6,500,000, which was recognized as

revenue on the date of the modification. No revenue was recognized in relation to the GSK Collaboration and License Agreement in 2023 or 2024.

*The GSK Termination and Transfer Agreement*

On April 6, 2023, the Company and GSK entered into a Termination and Transfer Agreement (the “Termination and Transfer Agreement”) regarding the return of rights and materials comprised within the PRAME and NY-ESO cell therapy programs. The parties will work collaboratively to ensure continuity for patients in ongoing lete-cel clinical trials forming part of the NY-ESO cell therapy program.

As part of the Termination and Transfer Agreement, sponsorship and responsibility for the ongoing IGENCYTE and long-term follow-up (“LTFU”) trials relating to the NY-ESO cell therapy program will transfer to the Company. In return for this, the Company received an upfront payment of £7.5 million in June 2023, following the signing of the agreement, and milestone payments of £3 million, £12 million, £6 million and £1.5 million in September and December 2023 and June and August 2024, respectively. No further payments are due from GSK under the Termination and Transfer Agreement.

The Company determined that GSK is a customer and has accounted for the Termination and Transfer Agreement under ASC 606 *Revenue from Contracts with Customers*. The Termination and Transfer Agreement is accounted for as a separate contract from the original Collaboration and License Agreement with GSK. The agreement was terminated in October 2022 and the termination became effective on December 23, 2022. The Company has identified the following performance obligations under the Termination and Transfer Agreement: (i) to take over sponsorship for the IGENCYTE trial and (ii) to take over sponsorship for the LTFU trial.

The aggregate transaction price at inception of the agreement was \$37,335,000 comprising the total £30,000,000 upfront and milestone payments. No value was ascribed to non-cash consideration and there was no variable consideration identified. The aggregate transaction price is allocated to the performance obligations depending on the relative standalone selling price of the performance obligations. In determining the best estimate of the relative standalone selling price, the Company considered the internal pricing objectives it used in negotiating the contract, together with internal data regarding the expected costs and a standard margin on those costs, for completing the trials. The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligation.

The Company expects to satisfy the performance obligations over time from the point that sponsorship of the active trials that make up the trial transfers and then over the period that the trial is completed, based on the number of patients transferred and still actively enrolled to date on the trial at a given period-end relative to the total estimated periods of active patient enrollment over the estimated duration of the trial.

The Company considers that this depicts the progress of the completion of the trials under the Termination and Transfer Agreement, as the status of patients on the trial is not directly affected by decisions that the Company might make relating to its own development of the NY-ESO cell therapy program.

The amount of the transaction price that is allocated to performance obligations that are unsatisfied or partially satisfied under the agreement as of December 31, 2024 was \$24,906,000, of which \$9,837,000 is allocated to the IGENCYTE performance obligation and \$15,069,000 is allocated to the LTFU performance obligation.

**Note 4 — Financial instruments**

The Company’s financial instruments consist primarily of cash and cash equivalents, marketable securities, restricted cash, accounts receivable and accounts payable.

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Assets and liabilities measured at fair value on a recurring basis based on Level 1, Level 2, and Level 3 fair value measurement criteria as of December 31, 2024 are as follows (in thousands):

	December 31, 2024	Fair value measurements using		
		Level 1	Level 2	Level 3
<b>Assets classified as cash equivalents:</b>				
U.S. Treasury securities	\$ 8,948	\$ —	\$ 8,948	\$ —
<b>Assets classified as available-for-sale debt securities:</b>				
Agency bonds	\$ 7,015	\$ —	\$ 7,015	\$ —
Corporate debt securities	6,224	6,224	—	—
U.S. Treasury securities	47,227	—	47,227	—
	<u>\$ 60,466</u>	<u>\$ 6,224</u>	<u>\$ 54,242</u>	<u>\$ —</u>

Assets and liabilities measured at fair value on a recurring basis based on Level 1, Level 2, and Level 3 fair value measurement criteria as of December 31, 2023 are as follows (in thousands):

	December 31, 2023	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
<b>Assets classified as cash equivalents:</b>				
Corporate debt securities	\$ 1,600	\$ 1,600	\$ —	\$ —
<b>Assets classified as available-for-sale debt securities:</b>				
Corporate debt securities	\$ 2,947	\$ 2,947	\$ —	\$ —

The Company estimates the fair value of available-for-sale debt securities and corporate debt securities classified as cash equivalents with the aid of a third-party valuation service, which uses actual trade and indicative prices sourced from third-party providers on a daily basis to estimate the fair value. If observed market prices are not available (for example, securities with short maturities and infrequent secondary market trades), the securities are priced using a valuation model maximizing observable inputs, including market interest rates.

*Significant concentration of credit risk*

The Company held cash and cash equivalents of \$91,139,000, marketable securities of \$60,466,000 and restricted cash of \$2,067,000 as of December 31, 2024. The cash and cash equivalents and restricted cash are held with multiple banks and the Company monitors the credit rating of those banks. The Company maintains cash balances in excess of amounts insured by the Federal Deposit Insurance Corporation in the United States and the U.K. Government Financial Services Compensation Scheme in the United Kingdom.

The Company had three collaboration customers during the year-ended December 31, 2024, which are Galapagos, Genentech and GSK, and two customers to whom product revenue sales were made. There were accounts receivable of \$1,454,000 and \$821,000 as of the years ended December 31, 2024 and 2023, respectively. The Company has been transacting with Galapagos since May 2024 and commercial customers since November 2024, during which time no credit losses have been recognized.

*Foreign exchange risk*

The Company is exposed to foreign exchange rate risk because it operates in the United Kingdom and the United States. Expenses are generally denominated in the currency in which the Company's operations are located,



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which are the United Kingdom and the United States. However, the U.K.-based subsidiary incurs significant research and development costs in U.S. dollars and, to a lesser extent, Euros.

The results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm the Company's business in the future. Management seeks to minimize this exposure by maintaining currency cash balances at levels appropriate to meet foreseeable expenses in U.S. dollars and pounds sterling. To date, the Company has not used forward exchange contracts or other currency hedging products to manage exchange rate exposure, although it may do so in the future. The exchange rate as of December 31, 2024, the last business day of the reporting period, was £1.00 to \$1.25.

*Interest rate risk*

Surplus cash and cash equivalents are invested in interest-bearing savings, money market funds, corporate debt securities and commercial paper from time to time. Investments in corporate debt securities are subject to fixed interest rates. The Company's exposure to interest rate sensitivity is impacted by changes in the underlying U.K. and U.S. bank interest rates and the fair market value of its corporate debt securities will fall in value if market interest rates increase. The Company's borrowings are subject to a variable interest rate if the Prime Rate increases above a contractual minimum but are effectively fixed if the Prime Rate is below this level. The Prime Rate is currently below the contractual minimum.

Management believes that an immediate one percentage point change in interest rates would not have a material effect on the fair market value of our portfolio and therefore does not expect the operating results or cash flows to be significantly affected by changes in market interest rates.

**Note 5 — Other current assets**

Other current assets consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Research and development credits receivable	\$ 12,929	\$ 46,098
Prepayments	10,033	9,954
Clinical materials	59	1,329
VAT receivable	1,599	—
Other current assets	3,170	2,412
	<u>\$ 27,790</u>	<u>\$ 59,793</u>

The Research and development credits receivable as of December 31, 2023 includes amounts receivable for claims covering the years ended December 31, 2023 and 2022 whereas the Research and development credits receivable as of December 31, 2024 primarily relates to the claim for the year ended December 31, 2024.

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**Note 6 — Property, plant and equipment, net**

Property and equipment, net consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Computer equipment	\$ 4,005	\$ 4,014
Laboratory equipment	34,904	33,951
Office equipment	1,004	1,009
Leasehold improvements	43,014	57,939
Assets under construction	275	53
	<u>83,202</u>	<u>96,966</u>
Less accumulated depreciation	(51,893)	(46,020)
	<u>\$ 31,309</u>	<u>\$ 50,946</u>

Depreciation expense was \$10,814,000, \$9,453,000, and \$5,266,000 for the years ended December 31, 2024, 2023 and 2022, respectively. An impairment loss of \$10,401,000 on leasehold improvements was recognized in the year ended December 31, 2024 with reductions of \$14,396,000 and \$4,072,000 to the associated cost and accumulated depreciation balances for leasehold improvements, respectively. See Note 17 for further details.

**Note 7 — Intangible assets, net**

Intangible assets, net consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Acquired software licenses	\$ 6,137	\$ 5,288
Licensed IP rights – completed technology used in R&D	195	197
In-licensed technology	3,115	—
	<u>9,447</u>	<u>5,485</u>
Less accumulated amortization	(5,567)	(5,155)
	<u>\$ 3,880</u>	<u>\$ 330</u>

Amortization expense was \$411,000, \$387,000 and \$809,000 for the years ended December 31, 2024, 2023 and 2022 respectively. The estimated aggregate amortization expense expected to be recorded in respect of these assets for each of the five years ended 2029 is \$652,000, \$552,000, \$416,000, \$247,000 and \$246,000 respectively.

**Note 8 — Operating leases**

The following table shows the lease costs for the years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
	2024	2023
<b>Lease cost:</b>		
Operating lease cost	\$ 6,755	\$ 5,791
Short-term lease cost	109	954
	<u>\$ 6,864</u>	<u>\$ 6,745</u>

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	Year ended	
	December 31,	
	2024	2023
<b>Other information:</b>		
Operating cash outflows from operating leases (in thousands)	\$ 6,980	\$ 5,863
	December 31,	
	2024	2023
Weighted-average remaining lease term - operating leases	6.3 years	5.4 years
Weighted-average discount rate - operating leases	10.6%	8.3%

The maturities of operating lease liabilities as of December 31, 2024 are as follows (in thousands):

	Operating leases	
2025	\$	6,805
2026		4,557
2027		4,193
2028		4,245
2029		4,298
after 2029		7,643
<b>Total lease payments</b>		<b>31,741</b>
Less: Imputed interest		(7,769)
<b>Present value of lease liability</b>	<b>\$</b>	<b>23,972</b>

The Company has operating leases in relation to property for office, manufacturing and research facilities. The maximum lease term without activation of termination options is to 2041.

On June 1, 2023, as part of the acquisition of TCR<sup>2</sup>, the Company became the lessee of three office, manufacturing and research facilities in Cambridge, Massachusetts. The Company retained TCR<sup>2</sup>'s previous classification for two of these leases as operating leases and, upon acquisition, the lease liabilities were measured at the present value of the remaining lease payments, as if the lease were a new lease of the Company at June 1, 2023. The right-of-use assets were initially measured at the same amount as the respective lease liabilities, adjusted to reflect favorable or unfavorable terms of the leases when compared with market terms.

The third lease had a remaining lease term of less than 12 months as of June 1, 2023, and the Company elected not to recognize a lease liability or right-of-use asset as of June 1, 2023. The rent associated with this lease was recognized on a straight-line basis over the remainder of the lease term.

Following the approval of TECELRA on August 1, 2024, the Company reassessed the conclusion about whether break and extension options would be exercised in determining the ASC 842 *Leases* ("ASC 842") lease term for its property in Philadelphia. As a result, the Company extended the ASC 842 lease term which resulted in a remeasurement of the lease liability using the current estimate of the Company's incremental borrowing rate. The amount of the remeasurement of the lease liability has been recognized as an adjustment to the corresponding right-of-use asset. The effect of the remeasurement was to increase the lease liability and the corresponding right-of-use asset by \$2,742,000.

**Note 9 — Accrued expenses and other current liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued clinical and development expenditure	\$ 11,931	\$ 12,351
Accrued commercial expenses and provisions	218	—
Accrued employee expenses	13,529	13,226
VAT payable	—	1,398
Other accrued expenditure	5,221	3,277
Other	2,020	51
	<u>\$ 32,919</u>	<u>\$ 30,303</u>

**Note 10 — Contingencies and commitments***Leases*

Lease payments under operating leases as of December 31, 2024 and information about the Company's lease arrangements are disclosed in Note 8.

*Capital commitments*

As of December 31, 2024, the Company had commitments for capital expenditure totaling \$1,477,000 primarily relating to future payments relating to intangible assets such as software licenses, of which the Company expects to incur \$894,000 within one year and \$583,000 within one to three years.

*Commitments for clinical materials, clinical trials, software and contract manufacturing*

As of December 31, 2024, the Company had non-cancellable commitments for purchase of clinical materials, contract manufacturing, commercial activities, maintenance, and up to \$16,558,000, which the Company expects to incur \$11,165,000 within one year, \$3,837,000 within one to three years and \$1,556,000 within three to five years. The amount and timing of these payments vary depending on the rate of progress of development. Future clinical trial expenses have not been included within the purchase commitments because they are contingent on enrollment in clinical trials and the activities required to be performed by the clinical sites. The Company's subcontracted costs for clinical trials and contract manufacturing were \$52,061,000, \$48,416,000 and \$54,689,000 for the years ended December 31, 2024, 2023, and 2022 respectively.

*MD Anderson Strategic Alliance*

On September 26, 2016, the Company announced that it had entered into a multi-year strategic alliance with The University of Texas MD Anderson Cancer Center ("MD Anderson") designed to expedite the development of T-cell therapies for multiple types of cancer. The Company and MD Anderson collaborated on a number of studies including clinical and preclinical development of the Company's T-cell therapies.

Under the terms of the agreement, the Company committed at least \$19,644,000 to fund studies. Payment of this funding was contingent on mutual agreement to study orders under the alliance agreement and the performance of set milestones by MD Anderson. The Company made an upfront payment of \$3,412,000 to MD Anderson in the year ended December 31, 2017 and subsequent milestone payments of \$2,326,000, \$3,549,000, \$454,000 and \$2,326,000 in the years ended December 31, 2018, 2020, 2021 and 2022, respectively. These costs were expensed to research and development as MD Anderson renders the services under the strategic alliance agreement.

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The collaboration ended on March 23, 2022, and enrolment has ceased, therefore the remaining clinical milestones totaling \$4,070,000 will not be met or become payable by the Company. The remaining preclinical work can continue until completion; the Company expects that the remaining billing upon completion less amounts invoiced to date totals approximately \$452,000.

On 2 December 2024, MD Anderson served litigation in the District Court of Harris County against Adaptimmune LLC relating to the strategic alliance. MD Anderson claims damages of over \$21 million (excluding legal fees and costs of court) caused by Adaptimmune's breach of contract. Alternatively, MD Anderson brings an action for quantum meruit, promissory estoppel, unjust enrichment, negligent misrepresentation and reformation. The Company provided its Original Answer, Affirmative Defenses, Special Exceptions and Counterclaims on January 22, 2025 denying all allegations of the MD Anderson petition and counterclaiming for breach of contract. MD Anderson filed a motion to dismiss the Company's counterclaim, Special Exceptions and Original Answer to the counterclaim denying all allegations in the counterclaim on 11 February 2025.

The case has not yet proceeded to discovery stage and the Company does not believe there is any merit to the claims being brought by MD Anderson. As such, no provision for a loss contingency has been made as of December 31, 2024.

*Universal Cells Research, Collaboration and License Agreement and Co-development and Co-commercialization agreement*

On November 25, 2015, the Company entered into a Research, Collaboration and License Agreement relating to gene editing and Human Leukocyte Antigen ("HLA") engineering technology with Universal Cells, Inc. ("Universal Cells"). The agreement was amended and re-stated as of January 13, 2020, primarily to reflect changes to the development plan agreed between the parties. The agreement was further amended as of July 22, 2022, primarily to make certain changes to development milestones and to agree on the status thereof, as agreed between the parties. Following the amendment, milestone payments of \$500,000, \$600,000 and \$400,000 were made in the year ended December 31, 2022. The upfront license and start-up fee and milestone payments were expensed to Research and development when incurred.

This Agreement was terminated by notice on January 27, 2023, effective 30 days following receipt of notice of termination. As a result of termination, all licenses between the parties to the Agreement ceased and each party was required to return all confidential information of the other party.

*Astellas Collaboration Agreement*

Under the Astellas Collaboration Agreement, described further in Note 3, if Adaptimmune had unilaterally developed a product with technology contributed by Astellas, Astellas could have been eligible to receive milestones and royalties relating to future commercialization and sales. As a result of the termination of the collaboration, Astellas no longer has the right to receive these milestones or royalties in future.

*Noile-Immune Collaboration Agreement*

On August 26, 2019, the Company entered into a collaboration and license agreement relating to the development of next-generation T-cell products with Noile-Immune. An upfront exclusive license option fee of \$2,500,000 was paid to Noile-Immune in 2019. This was recognized within Research and Development in the Consolidated Statement of Operations for the year ended December 31, 2019. Under the agreement, development and commercialization milestone payments up to a maximum of \$312,000,000 may be payable if all possible targets are selected and milestones achieved. Noile-Immune would also receive mid-single-digit royalties on net sales of resulting products.

*Alpine Collaboration Agreement*

On May 14, 2019, the Company entered into a Collaboration Agreement relating to the development of next-generation T-cell products with Alpine. The Company paid an upfront exclusive license option fee of \$2,000,000 to Alpine in June 2019. Under the agreement, Adaptimmune will pay Alpine for ongoing research and development funding costs and development and commercialization milestone payments up to a maximum of \$288,000,000 may be payable if all possible targets are selected and milestones achieved. The upfront payment of \$2,000,000 and the payments for ongoing research was recognized within Research and development in the Consolidated Statement of Operations for the year ended December 31, 2019. A further payment of \$1,000,000 was paid and recognized within Research and development in the Consolidated Statement of Operations for the year ended December 31, 2022. Alpine would also receive low single-digit royalties on worldwide net sales of applicable products.

*ThermoFisher License Agreement*

In 2012, the Company entered into a series of license and sub-license agreements with Life Technologies Corporation, part of ThermoFisher Scientific, Inc. (“ThermoFisher”) that provided the Company with a field-based license under certain intellectual property rights owned or controlled by ThermoFisher. The Company paid upfront license fees of \$1,000,000 relating to the license and sublicense agreements and had an obligation to pay minimum annual royalties, milestone payments and a low single-digit running royalty payable on the net selling price of each licensed product. The minimum annual royalties have been expensed as incurred. The patents underlying these licenses expired in January 2024 and the Company is no longer obligated to pay further milestones or royalties.

*Regulatory Assay Development*

As part of the process of obtaining regulatory approval for its products, the Company entered into various agreements for the development of assays for commercial supply, some of which have milestone or other payments that trigger on or after regulatory approval is received from the FDA, and upon the occurrence of future sales or commercial usage of the respective assay.

**Note 11 — Stockholders’ equity**

*Ordinary shares*

Subject to any other provisions of our articles of association and without prejudice to any special rights, privileges or restrictions as to voting attached to any shares forming part of our share capital, the voting rights of shareholders are as follows. On a show of hands, each shareholder present in person, and each duly authorized representative present in person of a shareholder that is a corporation, has one vote. On a show of hands, each proxy present in person who has been duly appointed by one or more shareholders entitled to vote on a resolution has one vote, but a proxy has one vote for and one vote against a resolution if, in certain circumstances, the proxy is instructed by more than one shareholder to vote in different ways on a resolution. On a poll, each shareholder present in person or by proxy or (being a corporation) by a duly authorized representative has one vote for each share held by the shareholder. We are prohibited (to the extent specified by the Companies Act 2006) from exercising any rights to attend or vote at meetings in respect of any shares held by the Company as treasury shares.

Subject to the Companies Act 2006 and the provisions of all other relevant legislation, we may by ordinary resolution declare dividends out of our profits available for distribution in accordance with the respective rights of shareholders but no such dividend shall exceed the amount recommended by the directors. If, in the opinion of the directors, our profits available for distribution justify such payments, the directors may from time to time pay interim dividends to the holders of any class of shares. Subject to any special rights attaching to or terms of issue of any shares, all dividends shall be declared and paid according to the amounts paid up on the shares on which the dividend is paid. No dividend shall be payable to us in respect of any shares held by us as treasury shares (except to the extent permitted by the Companies Act 2006 and any other relevant legislation). As of December 31, 2024, Adaptimmune Therapeutics plc and Adaptimmune Limited have accumulated net losses and, accordingly, no profits available for distribution out of which to declare or pay dividends.

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Subject to any special rights attaching to or the terms of issue of any shares, on any winding-up of the Company our surplus assets remaining after satisfaction of our liabilities will be distributed among our shareholders in proportion to their respective holdings of shares and the amounts paid up on those shares.

Effective from May 14, 2024, the Directors were generally authorized to allot new shares or to grant rights to subscribe for or to convert any security into shares in the Company up to a maximum aggregate nominal amount of £505,881.00. This authority will expire on the earlier of the conclusion of the Company's annual general meeting in 2025 and June 30, 2025 (unless previously renewed, varied or revoked). Effective from May 14, 2024, the Directors were also empowered to allot equity securities for cash, pursuant to their general authority to allot described in this paragraph, without first offering them to existing shareholders in proportion to their existing holdings up to an aggregate maximum nominal amount of £505,881.00. This power will expire on the earlier of the conclusion of the Company's annual general meeting in 2025 and June 30, 2025 (unless previously renewed, varied or revoked).

*At-the-Market Offerings*

On April 8, 2022 the Company entered into a sales agreement with Cowen (the "Sales Agreement") under which we may from time to time issue and sell ADSs representing our ordinary shares through Cowen in at-the-market "ATM" offerings for an aggregate offering price of up to \$200 million. In the year ended December 31, 2024, the Company sold 27,278,176 ADSs under the Sales Agreement representing 163,669,056 ordinary shares resulting in net proceeds to the Company of \$29,155,317 after deducting commissions payable under the Sales Agreement and estimated issuance costs. As of December 31, 2024, approximately \$156,228,841 remained available for sale under the Sales Agreement.

**Note 12 — Share-based compensation**

The Company has granted options over ordinary shares in Adaptimmune Therapeutics plc under the following option plans: (i) the Adaptimmune Therapeutics plc Employee Share Option Scheme (adopted on January 14, 2016), (ii) the Adaptimmune Therapeutics plc 2015 Share Option Scheme (adopted on March 16, 2015) and (iii) the Adaptimmune Therapeutics plc Company Share Option Plan (adopted on March 16, 2015).

The Adaptimmune Therapeutics plc Company Share Option Plan is a tax efficient option scheme intended to comply with the requirements of Schedule 4 to the Income Tax (Earnings and Pensions) Act 2003 of the United Kingdom, which provides for the grant of company share option plan ("CSOP") options. Grants may not exceed the maximum value of £60,000 per participant for the shares under the option, which is a CSOP compliance requirement.

Generally, the vesting dates for the options granted under these plans up to December 31, 2024 are 25% on the first anniversary of the grant date and 75% in monthly installments over the following three years. However, the options

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granted to non-executive directors under the Adaptimmune Therapeutics plc 2015 Share Option Scheme vest and become exercisable as follows:

Options granted to non-executive directors on May 11, 2015:	Immediately on grant date
Options granted to a non-executive director on June 23, 2016:	25% on the first anniversary of the grant date and 75% in monthly installments over the following two years
Options granted to non-executive directors on August 11, 2016:	100% on the first anniversary of the grant date
Options granted to non-executive directors on November 28, 2016:	25% on the first anniversary of the grant date and 75% in monthly installments over the following two years
Options granted to non-executive directors on July 3, 2017:	100% on the first anniversary of the grant date
Options granted to non-executive directors on June 22, 2018:	100% on the first anniversary of the grant date
Options granted to a non-executive director on July 5, 2018:	25% on the first anniversary of the grant date and 75% in monthly instalments over the following two years
Options granted to non-executive directors on July 2, 2019:	100% on the first anniversary of the grant date
Options granted to non-executive directors on July 1, 2020:	100% on the first anniversary of the grant date
Options granted to non-executive directors on July 1, 2021:	100% on the first anniversary of the grant date
Options granted to non-executive directors on July 1, 2022:	100% on the first anniversary of the grant date
Options granted to non-executive directors on July 3, 2023:	100% on the first anniversary of the grant date
Options granted to a non-executive director on November 1, 2023:	25% on the first anniversary of the grant date and 75% in monthly instalments over the following two years
Options granted to non-executive directors on January 15, 2024:	100% on the first anniversary of the grant date
Options granted to non-executive directors on July 1, 2024:	100% on the first anniversary of the grant date

Effective from January 2018, the Company has also granted restricted stock unit style options (“RSU-style options”). The RSU-style options over ordinary shares in Adaptimmune Therapeutics plc were granted under the Adaptimmune Therapeutics plc Employee Share Option Scheme (adopted on January 14, 2016). These options have an exercise price equal to the nominal value of an ordinary share, of £0.001, and generally vest over four years, with 25% on the first, and each subsequent, anniversary of the grant date.

Options granted under these plans are not subject to performance conditions. The contractual term of options granted under these plans is ten years.

The maximum aggregate number of options which may be granted under these plans and any incentive plans adopted by the Company cannot exceed a scheme limit that equates to 8% of the initial fully diluted share capital of the Company immediately following its IPO plus an automatic annual increase of an amount equivalent to 4% of the issued share capital on each 30 June (or such lower number as the Board, or an appropriate committee of the Board, may determine). The automatic increase is effective from July 1, 2016.

Prior to December 31, 2014, the Company granted options to purchase ordinary shares in Adaptimmune Limited under three option schemes:

(i) The Adaptimmune Limited Share Option Scheme was adopted on May 30, 2008. Under this scheme Enterprise Management Incentive (“EMI”) options (which are potentially tax-advantaged in the United Kingdom) have been granted (subject to the relevant conditions being met) to its employees who are eligible to receive EMI options



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under applicable U.K. tax law and unapproved options (which do not attract tax advantages) have been granted to its employees who are not eligible to receive EMI options, and to its Directors and consultants. In May 2014, the Company no longer qualified for EMI status and since that date, no further EMI options were granted under this scheme; however, unapproved options have been under granted under this scheme since that date.

(ii) The Adaptimmune Limited 2014 Share Option Scheme was adopted on April 11, 2014. EMI options were granted (subject to the relevant conditions being met) under this scheme to our employees who are eligible to receive EMI options under applicable U.K. tax law. Unapproved options were granted to its employees who are not eligible to receive EMI options and to directors. In May 2014, the Company no longer qualified for EMI status and since that date, no further EMI options were granted under this scheme; however, unapproved options have been under granted under this scheme since that date.

(iii) The Adaptimmune Limited Company Share Option Plan was adopted on December 16, 2014. This scheme allowed the grant of options to our eligible employees prior to the Company's corporate reorganization in 2015. This scheme is a tax efficient option scheme and options were granted on December 19, 2014 and on December 31, 2014 to our part-time and full-time employees.

As part of the corporate reorganization in connection with our IPO, the holders of options granted under these schemes over ordinary shares of Adaptimmune Limited were granted equivalent options on substantially the same terms over ordinary shares of Adaptimmune Therapeutics plc ("Replacement Options") in exchange for the release of these options. The Company does not intend to grant any further options under these schemes.

As of December 31, 2024, all the Replacement Options under the Adaptimmune Limited schemes have vested.

The contractual life of options granted under these schemes is ten years.

The following table shows the total share-based compensation expense included in the Consolidated Statements of Operations (in thousands):

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Research and development	\$ 3,875	\$ 3,061	\$ 6,264
Selling, general and administrative	8,176	8,712	11,976
	<b>\$ 12,051</b>	<b>\$ 11,773</b>	<b>\$ 18,240</b>

As of December 31, 2024, there was \$8,493,000 of total unrecognized compensation cost related to stock options granted but not vested under the plans. That cost will be recognized over an expected remaining weighted-average period of 2.47 years. The following table shows information about share options granted:

	Year ended December 31,		
	2024	2023	2022
Number of options over ordinary shares granted	55,282,716	60,891,430	31,826,293
Weighted average fair value of ordinary shares options	\$ 0.12	\$ 0.12	\$ 0.37
Number of additional options with a nominal exercise price granted	34,560,096	27,375,252	24,248,424
Weighted average fair value of options with a nominal exercise price	\$ 0.15	\$ 0.27	\$ 0.51

The following table summarizes all stock option activity for the year ended December 31, 2024:

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	Options	Weighted average exercise price per option	Average remaining contractual term (years)	Aggregate intrinsic value (thousands)
Outstanding at January 1, 2024	191,150,175	£ 0.41		
Changes during the period:				
Granted	89,842,812	£ 0.08		
Exercised	(8,976,462)	£ 0.01		
Expired	(14,454,205)	£ 0.52		
Forfeited	(4,175,144)	£ 0.07		
<b>Outstanding at December 31, 2024</b>	<b>253,387,176</b>	<b>£ 0.31</b>	<b>6.9</b>	<b>£ 4,698</b>
Exercisable at December 31, 2024	129,110,391	£ 0.50	5.1	£ 873

The following table summarizes information about stock options granted based on the market value at grant date which were outstanding as of December 31, 2024:

	Options	Weighted average exercise price per option	Average remaining contractual term (years)	Aggregate intrinsic value (thousands)
Outstanding at January 1, 2024	147,670,115	£ 0.53		131
Changes during the period:				
Granted	55,282,716	£ 0.12		
Exercised	(622,278)	£ 0.09		
Expired	(14,378,110)	£ 0.53		
Forfeited	(1,098,173)	£ 0.27		
<b>Outstanding at December 31, 2024</b>	<b>186,854,270</b>	<b>£ 0.41</b>	<b>6.4</b>	<b>£ 4</b>
Exercisable at December 31, 2024	116,768,430	£ 0.49	5.0	£ 2

The following table summarizes information about RSU-style options which were outstanding as of December 31, 2024:

	Options	Average remaining contractual term (years)	Aggregate intrinsic value (thousands)
Outstanding at January 1, 2024	43,480,060	8.1	4,470
Changes during the period:			
Granted	34,560,096		
Exercised	(8,354,184)		
Expired	(76,095)		
Forfeited	(3,076,971)		
<b>Outstanding at December 31, 2024</b>	<b>66,532,906</b>	<b>8.1</b>	<b>£ 4,695</b>
Exercisable at December 31, 2024	12,341,961	6.1	£ 871

There were 8,976,462, 14,614,410 and 5,823,534 share options exercised in the years ended December 31, 2024, 2023 and 2022 respectively. In the years ended December 31, 2024, 2023 and 2022 the total intrinsic value of stock options exercised was \$1,281,000, \$2,527,000 and \$2,368,000, respectively and the cash received from exercise of stock options was \$77,000, \$256,000 and \$50,000 respectively. The Company recognizes tax benefits arising on the exercise of stock options regardless of whether the benefit reduces current taxes. The tax benefit arising on the exercise of stock options was \$617,000, \$541,000 and \$488,000 for the years ended December 31, 2024, 2023 and 2022 respectively. The Company satisfies the exercise of stock options through newly issued shares.

Exercise price	Outstanding			Exercisable		
	Total share options	Weighted-average remaining contractual life	Weighted-average exercise price	Total share options	Weighted-average exercise price	
£ 0.001	66,532,906	8.1	£ 0.00	12,341,961	£ 0.00	
0.01 - 0.25	74,588,395	8.5	0.13	19,963,611	0.15	
0.26 - 0.50	48,832,463	6.6	0.37	34,325,165	0.39	
0.51 - 0.75	35,763,545	3.6	0.59	35,390,721	0.59	
0.76 - 1.00	21,844,478	4.0	0.84	21,549,378	0.84	
1.01 - 1.50	3,311,907	4.4	1.30	3,274,431	1.30	
1.51 - 2.00	1,879,690	4.3	1.67	1,719,718	1.67	
Over 2.00	633,792	6.0	4.30	545,406	4.47	
<b>Total</b>	<b>253,387,176</b>	<b>6.9</b>	<b>£ 0.31</b>	<b>129,110,391</b>	<b>£ 0.50</b>	

The fair value of the stock options granted during the period was calculated using the Black-Scholes option-pricing model using the following assumptions:

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Expected term	5 years	5 years	5 years
Expected term (TCR2 replacement options)	—	0.5 - 4 years	—
Expected volatility	104-105%	84-113%	99-101%
Risk free rate	3.55-3.99%	3.27-4.52%	0.94-3.90%
Expected dividend yield	0%	0%	0%

The expected term of the option is based on management judgment. The life of the options depends on the option expiration date, volatility of the underlying shares and vesting features. We do not have sufficient history to determine the expected life based on internal data and therefore the estimate is based on empirical data. For Replacement Options issued former to TCR<sup>2</sup> employees as part of the acquisition of TCR<sup>2</sup> the expected term of the options was adjusted to account for options that were already fully or partially vested on the grant date and for known factors that would impact the expected term such as redundancy post-acquisition.

Management uses historical data to determine the volatility of the Company's share price. The risk-free rate is based on the Bank of England's estimates of the gilt yield curve as of the respective grant dates.

**Note 13 — Income taxes**

Loss before income tax expense is as follows (in thousands):

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
U.S.	\$ (10,695)	\$ (9,597)	\$ (3,245)
U.K.	(56,543)	(102,938)	(159,714)
Loss before income tax expense	<b>\$ (67,238)</b>	<b>\$ (112,535)</b>	<b>\$ (162,959)</b>

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The amount allocated to the U.S. in the year ended December 31, 2023, includes the \$22,049,000 gain on bargain purchase.

The components of income tax expense are as follows (in thousands):

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
United States:			
Federal	\$ 3,509	\$ 1,301	\$ 2,492
State and local	67	9	5
U.K.	—	26	—
<b>Total current tax expense</b>	<b>3,576</b>	<b>1,336</b>	<b>2,497</b>
United States:			
Federal	—	—	—
State and local	—	—	—
U.K.	—	—	—
<b>Total deferred tax expense</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Total income tax expense</b>	<b>\$ 3,576</b>	<b>\$ 1,336</b>	<b>\$ 2,497</b>

As of December 31, 2024 and 2023 the tax effects of temporary differences and carry forwards that give rise to deferred tax assets and liabilities were as follows (in thousands):

	December 31, 2024	December 31, 2023
<b>Deferred tax liabilities</b>		
Property, plant and equipment	\$ (1,010)	\$ (4,954)
Operating lease right-of-use assets	(1,964)	(1,780)
Other	(637)	(365)
<b>Total</b>	<b>(3,611)</b>	<b>(7,099)</b>
<b>Deferred tax assets</b>		
Share-based compensation expense	15,773	15,039
Property, plant and equipment	183	391
Intangible assets	1,372	1,392
Operating lease liabilities	2,658	2,556
Net operating loss and tax credit carryforwards	248,582	241,337
Capitalized research and development expenditure	41,805	37,699
Other	2,726	3,605
<b>Total</b>	<b>313,099</b>	<b>302,019</b>
Valuation allowance	(309,488)	(294,920)
	<b>3,611</b>	<b>7,099</b>
<b>Net deferred tax asset/(liability)</b>	<b>\$ —</b>	<b>\$ —</b>

The valuation allowance is primarily related to deferred tax assets for operating loss and tax credit carry-forwards and temporary differences relating to share-based compensation expense and research and development expenditure. Deferred tax assets have been recognized without a valuation allowance to the extent supported by reversing taxable temporary differences. A valuation allowance has been provided over the remaining deferred tax assets, which management considered are not more likely than not of being realized after weighing all available positive and negative evidence including cumulative losses in recent years and projections of future taxable losses.

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The movements in the deferred tax asset valuation allowance for the year ended December 31, 2024 and 2023 are as follows (thousands):

	2024	2023
Valuation allowance at January 1,	\$ 294,920	\$ 160,512
Valuation allowance for deferred tax assets acquired from TCR <sup>2</sup>	—	114,294
Increase in valuation allowance through net loss	14,321	21,076
Increase /(decrease) in valuation allowance through other comprehensive loss	2,454	(8,042)
Foreign currency translation adjustments	(2,207)	7,080
Net change in the valuation allowance	14,568	134,408
<b>Valuation allowance at December 31,</b>	<b>\$ 309,488</b>	<b>\$ 294,920</b>

Reconciliation of the U.K. statutory income tax rate, the income tax rate of the country of domicile of the Company, to the Company's effective income tax rate is as follows (in percentages):

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
U.K. tax rate	25.0 %	23.5 %	19.0 %
Tax-exempt reimbursable tax credits included within pretax Research and development expense	3.5 %	2.5 %	3.6 %
Income not taxable	0.5 %	5.3 %	— %
Surrender of R&D expenditures for R&D tax credit refund	(20.2)%	(13.3)%	(10.5)%
Expenses not deductible	(1.9)%	(2.3)%	(0.3)%
Change in valuation allowances	(21.3)%	(18.9)%	(18.8)%
Difference in tax rates	— %	0.0 %	5.5 %
R&D tax credits generated	4.5 %	3.1 %	2.1 %
Other	4.6 %	(1.0)%	(2.1)%
<b>Effective income tax rate</b>	<b>(5.3)%</b>	<b>(1.1)%</b>	<b>(1.5)%</b>

The Company is headquartered in the United Kingdom and has subsidiaries in the United Kingdom and the United States. The Company incurs tax losses in the United Kingdom. The U.K. corporate income tax rate for the year ended December 31, 2024 was 25%, and 23.5% and 19% for the years ended December 31, 2023 and 2022, respectively. Adaptimmune LLC in the United States has generated taxable profits due primarily to a service agreement between Adaptimmune LLC and the Company's subsidiaries in the United Kingdom. The U.S. federal corporate income tax rate was 21% for the years ended December 31, 2024, 2023 and 2022, respectively. TCR<sup>2</sup> has incurred net losses in the United States since acquisition. TCR<sup>2</sup>'s deferred tax assets for operating loss carryforwards and other tax attributes are reduced by a valuation allowance to the amount supported by reversing taxable temporary differences because there is currently no indication that we will make sufficient taxable profits to utilize these deferred tax assets. Income not taxable primarily relates to the gain on bargain purchase, which only arises at a consolidated level and is not taxable.

The United Kingdom's Finance Act 2021, which was enacted on June 10, 2021, maintained the corporate income tax rate at 19% up until the year commencing April 1, 2023, at which point the rate rose to 25%. As of December 31, 2024, the Company used a 25% and 21% tax rate in respect of the measurement of deferred taxes existing in the U.K. and the U.S., respectively, which reflects the currently enacted tax rates and the anticipated timing of the reversing of the deferred tax balances.

As of December 31, 2024, we do not have unremitted earnings in our U.S. subsidiaries.

As of December 31, 2024, we had U.K. net operating loss carryforwards of approximately \$569,858,000, U.K. expenditure credit carryforwards of \$1,576,000, U.S. federal and state net operating loss carryforwards of approximately \$395,887,000 and U.S. capitalized research and development expenditure of \$199,070,000. Unsurrendered U.K. net operating loss carryforwards can be carried forward indefinitely to be offset against future taxable profits; however, this

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is restricted to an annual £5,000,000 allowance in each standalone company or group and above this allowance, there will be a 50% restriction in the profits that can be covered by losses brought forward. U.K. tax credit carryforwards can be carried forward indefinitely to be offset against future tax liabilities of the company. U.S. tax credit carryforwards can be carried forward for 20 years to be offset against future tax liabilities. U.S. capitalized research and development expenditure relates to certain research and development costs that are capitalized for tax purposes and amortized over a period of years rather than deducted from taxable income in the year they arise; these primarily arise due to Section 174 of the U.S. Internal Revenue Code which has a 5 and 15 year amortization period for domestic and foreign-incurred costs, respectively.

Our tax returns are under routine examination in the U.K. and U.S. tax jurisdictions. The scope of these examinations includes, but is not limited to, the review of our taxable presence in a jurisdiction, our deduction of certain items, our claims for research and development credits, our compliance with transfer pricing rules and regulations and the inclusion or exclusion of amounts from our tax returns as filed. The Company is no longer subject to examinations by tax authorities for the tax years 2017 and prior in the U.K. and there are no ongoing enquiries in the U.K. However, U.K. net operating losses from the tax years 2017 and prior would be subject to examination if and when used in a future tax return to offset taxable income. Our U.K. income tax returns have been accepted by His Majesty's Revenue and Customs through the period ended December 31, 2018. The Company is subject to examinations by taxing authorities in the United States for all tax years 2021 through 2024. We are also subject to audits by U.S. state taxing authorities where we have operations.

Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of uncertainties in the tax law. As of December 31, 2024 and 2023, the Company had no unrecognized tax benefits.

**Note 14 — Geographic and segmental information**

*Operations by geographic area*

Product revenue represents sales of TECELRA. All product revenue was derived in the United States.

Development revenue represents recognized income from the Astellas Collaboration Agreement, the Galapagos Collaboration and License Agreement, the Genentech Collaboration and License Agreement, the GSK Collaboration and License Agreement and the GSK Termination and Transfer Agreement. All development revenue was derived in the United Kingdom.

Long-lived assets (excluding intangibles, deferred tax and financial instruments) were located as follows (in thousands):

	December 31, 2024	December 31, 2023
U.K.	\$ 24,264	\$ 40,988
U.S.	26,954	30,720
<b>Total long-lived assets</b>	<b>\$ 51,218</b>	<b>\$ 71,708</b>

*Major customers:*

During the year ended December 31, 2024, 0%, 93% and 7% of the Company's revenues were generated from Galapagos, Genentech and GSK, respectively.

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*Segment reporting:*

The Company has one reportable segment relating to the research, development and commercialization of its novel cell therapies. The segment derives its current revenues from research and development collaborations.

The Company's CODM, its Chief Executive Officer and the senior leadership team (comprising the Executive Team members and three senior vice presidents), manages the Company's operations on an integrated basis for the purposes of allocating resources. When evaluating the Company's financial performance, the CODM regularly reviews total revenues, total expenses and expenses by function and the CODM makes decisions using this information on a global basis.

	Year ended December 31,		
	2024	2023	2022
Revenue	\$ 178,032	\$ 60,281	\$ 27,148
Less:			
Research	(13,404)	(13,228)	(22,912)
CMC and Quality	(61,350)	(60,466)	(61,850)
Biomarkers	(8,227)	(4,235)	(8,977)
Development and Compliance	(52,737)	(43,863)	(43,614)
Infrastructure management and Facilities	(31,739)	(28,481)	(25,266)
Commercial and Commercial planning	(15,860)	(3,344)	(4,329)
Support and corporate functions	(45,186)	(43,614)	(32,483)
Other segment expenses <sup>(a)</sup>	(18,289)	(2,791)	8,318
<b>Total operating expenses</b>	<b>(246,792)</b>	<b>(200,022)</b>	<b>(191,113)</b>
<b>Operating loss</b>	<b>(68,760)</b>	<b>(139,741)</b>	<b>(163,965)</b>
Interest income	6,596	5,964	1,542
Interest expense	(3,348)	—	—
Gain on bargain purchase	—	22,049	—
Other income (expense), net	(1,726)	(807)	(536)
Income tax expense	(3,576)	(1,336)	(2,497)
<b>Segment and consolidated net loss</b>	<b>\$ (70,814)</b>	<b>\$ (113,871)</b>	<b>(165,456)</b>

<sup>(a)</sup>Other segment expenses includes reimbursements receivable for research and development tax and expenditure credits, depreciation, amortization, impairment of long-lived assets and share-based compensation expenses which are included in Note 2q, Note 6, Note 7, Note 17 and Note 12, respectively. Restructuring charges are included in Support and corporate functions and disclosed in Note 17.

The main measure of assets reviewed by the CODM is the Company's cash and cash equivalents and marketable securities. Total cash outflows relating to additions to long-lived assets have been disclosed in the Consolidated Statements of Cash Flows as cash outflows from investing activities.

**Note 15 – Inventory**

On August 1, 2024, the Company received FDA approval for TECELRA for the treatment of advanced MAGE-A4+ synovial sarcoma in adults with certain HLA types who have received prior chemotherapy, and commenced capitalization of inventory from this date.

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Prior to August 1, 2024, regulatory approval and subsequent commercialization of TECELRA, and thus the possibility of future economic benefits from TECELRA sales, were not considered probable and inventory-related costs were expensed as incurred; as such, the inventory recognized on the balance sheet does not include any pre-launch inventory. At December 31, 2024, the gross value of pre-launch inventory held but not recognized was \$7,103,000, which includes inventory that could be used for either clinical or commercial purposes.

The components of inventory are as follows:

	December 31, 2024	December 31, 2023
Raw materials	\$ 7,236	\$ —
Work-in-progress	84	—
Finished goods	—	—
<b>Total inventory, net</b>	<b>\$ 7,320</b>	<b>\$ —</b>

In addition to the above, the Company recognized an asset of \$1,865,000 at December 31, 2024 relating to pre-purchases of raw materials that are still under production and have not yet been delivered.

**Note 16 – Borrowings**

On May 14, 2024 (the “Closing Date”), we entered into a Loan and Security Agreement (the “Loan Agreement”), with several banks and other financial institutions or entities and Hercules Capital, Inc. (“Hercules Capital”), for a term loan facility of up to \$125.0 million (the “Term Loan”), consisting of a term loan advance in the aggregate principal amount equal to \$25.0 million on the Closing Date (the “Tranche 1 Advance”), and three further term loan advances available to the Company subject to certain terms and conditions in aggregate principal amounts of \$25.0 million, \$5.0 million and \$30.0 million, respectively, and a term loan advance available in the sole discretion of the lenders and subject to certain terms and conditions in the aggregate principal amount of \$40.0 million. The proceeds of the Term Loan will be used solely to repay related fees and expenses in connection with the Loan Agreement and for working capital and general corporate purposes.

The Term Loan attracts interest on the outstanding principal in the form of both cash and payment-in-kind (“PIK”) interest. The cash interest rate is the greater of the Prime Rate plus 1.15% and 9.65% and is paid monthly in arrears. The PIK interest rate is 2% per annum. The outstanding principal used to determine both the cash and PIK interest is inclusive of capitalized PIK interest. The Term Loan also attracts an End of Term Charge of 5.85% payable on maturity which is based on the aggregate original principal amount (i.e. excluding capitalized PIK interest).

The Term Loan matures on June 1, 2029 and payments are interest-only until the June 1, 2027 (the “Amortization Date”) after which the monthly payments include repayments of both principal and interest. The Amortization Date can be extended if certain criteria are met and the Company chooses to extend the date. The final Term Loan Maturity Date cannot be extended.

The Term Loan is secured by a lien on substantially all of Borrower’s existing or after-acquired assets, including intellectual property, subject to customary exceptions. In addition, the Loan Agreement contains customary closing and commitment fees, prepayment fees and provisions, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring the Company to maintain certain levels of cash in accounts subject to a control agreement in favor of Hercules Capital (the “Qualified Cash”) during the period commencing on January 1, 2025 (which initial commencement date is subject to adjustment if certain performance milestones are met) and at all times thereafter, provided that if the Company has achieved certain performance milestones, the amount of Qualified Cash is subject to certain reductions. The Loan Agreement also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, the occurrence of certain events that could reasonably be expected to have a “material adverse effect” as set forth in the Loan Agreement, cross acceleration to third-party indebtedness and certain events relating to bankruptcy or insolvency.



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Each loan tranche has been identified as a separate unit of account within the scope of ASC 835-30 *Imputation of interest*, with the Tranche 1 Advance constituting a debt instrument and the remaining tranches being loan commitments until if and when each commitment is drawn, at which point they will become debt instruments.

On May 14, 2024, the Company drew down the Tranche 1 Advance of \$25,000,000 and received proceeds of \$24,500,000 after charges payable to Hercules Capital. The Tranche 1 Advance was initially recognized at \$24,750,000. On August 13, 2024, the Company drew down the Tranche 2 Advance of \$25,000,000 (the “Tranche 2 Advance,” and, together with the Tranche 1 Advance, “Tranches” and each a “Tranche”) and received proceeds of \$25,000,000. The Tranche 2 Advance was initially recognized at \$24,750,000. At December 31, 2024 the face value of the outstanding principal (including capitalized PIK interest) on the Term Loan (including both Tranches) was \$50,520,000, less unamortized discount of \$468,000 and plus accreted value of the End of Term Charge of \$185,000 based on the imputed interest rate of 13.7%. No qualifying debt issuance costs were incurred in relation to either Tranche.

At December 31, 2024, the fair value of the Term Loan was \$51,622,000. The fair value of the Term Loan is a Level 2 measurement based on observable inputs including the contractual term of the instrument and market interest rates, notably the Prime Rate.

The aggregate maturity of the term loan for the next five years from December 31, 2024 is as follows:

	<u>Maturity</u>
2025	\$ —
2026	—
2027	12,767
2028	23,601
2029	17,909
<b>Total principal repayments</b>	<b>\$ 54,277</b>
<b>Composition of principal repayments</b>	
Original principal	\$ 50,000
Capitalized PIK interest	4,277
<b>Total principal repayments</b>	<b>\$ 54,277</b>

The payments included in the table include capitalized PIK interest, as this forms part of the principal balance to be repaid once incurred. Payments relating to cash interest and the End of Term Charge are excluded as they do not constitute repayments of the principal.

On March 24, 2025 the Company agreed to pre-pay \$25.0 million of the Term Loan, see Note 19 for further details.

**Note 17 – Restructuring programs**

*2024-2025 Restructuring program*

Reduction in workforce

On November 13, 2024 the Company announced a restructuring plan that aims to prioritize its commercial sarcoma franchise and certain research and development programs. As part of this restructuring, the Company is executing against a plan to achieve an approximately 33% reduction in workforce. The majority of the reduction in workforce was completed during the first quarter of 2025.

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The redundancy process was initiated in the fourth quarter of 2024, with most employees leaving in the first quarter of 2025. Employees in certain roles will be retained during a transition period beyond the first quarter of 2025. Once the redundancy program is completed, it will result in a reduction of approximately 29% of global headcount.

The redundancy packages to be paid to departing staff comprise a combination of contractual termination benefits, relating to payments that arise from terms of employment contracts and statutory redundancy pay, and one-time employee termination benefits that were provided or enhanced specifically for this redundancy process. Due to the structure of the redundancy scheme and the different employment regulations affecting the Company's U.K. and U.S. employees, some of the expense associated with the one-time employee termination benefits was recognized over the remaining period of employee service to be rendered. Contractual termination benefits and other one-time employee termination benefits were expensed and recognized in the year ended December 31, 2024. All expenses have been recognized in Selling, general and administrative expenses in the Statement of Operations.

The amounts expected to be incurred in relation to the redundancy program were as follows:

	Contractual termination benefits	One-time employee termination benefits	Total restructuring cost
Amount incurred in the year ended, and cumulative amount incurred to, December 31, 2024	\$ 4,102	\$ 1,809	\$ 5,911
Remaining amount expected to be incurred in future periods	—	1,938	1,938
<b>Total amount expected to be incurred</b>	<b>\$ 4,102</b>	<b>\$ 3,747</b>	<b>\$ 7,849</b>

The table below is a summary of the changes in the restructuring provision in the consolidated balance sheets in the year ended December 31, 2024:

	Contractual termination benefits	One-time employee termination benefits	Total restructuring provision
Liability at December 31, 2023	\$ —	\$ —	\$ —
Costs incurred and charged to selling, general and administrative expenses	4,130	1,820	5,950
Effects of foreign exchange rates	(28)	(11)	(39)
<b>Liability at December 31, 2024</b>	<b>\$ 4,102</b>	<b>\$ 1,809</b>	<b>\$ 5,911</b>

Impairment of long-lived assets classified as held and used

Due to the headcount reduction and reprioritization of certain programs as part of the restructuring announced in November 2024, the Company identified indications of impairment relating to its UK facilities. The reduction in headcount is expected to mostly affect UK-based staff with a reduction in the number of programs being worked on in the UK; as such, it is no longer expected that the Company will fully utilize its UK facilities.

The Company used a market approach to determine the fair value, based on the potential current market rentals that could be achieved for the asset groups and discounted using property yield rates for similar buildings. The fair value measurement for the UK facilities is a Level 2 measurement.

The fair value of the asset group comprising the right-of-use and leasehold improvements assets relating to the UK manufacturing facility was determined to be lower than its carrying amount and an impairment loss was recognized. However, the fair value of the individual right-of-use asset for the building was determined to be in excess of its carrying amount; as such, the impairment loss of \$10,401,000 was allocated solely to the leasehold improvement assets in the

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asset group resulting in the leasehold improvement assets being written down to \$3,900,000 with a reduction of \$14,396,000 and \$4,072,000 in cost and accumulated depreciation, respectively.

The fair value of the asset group comprising the UK headquarters and laboratory space was determined to be in excess of its carrying amount, so no impairment loss was recognized.

No impairment indicators were identified in relation to assets held by our US subsidiaries on the basis that the refocusing of activities will prioritize programs that are primarily based in the US and which are commercial and revenue-generating, specifically our TECELRA product, or closer to commercialization, such as our pre-commercial *lete-cel* product. In addition, the reduction in headcount in the US is less significant than the reduction in the UK.

*2022-3 Restructuring program*

On November 8, 2022, the Company announced that in order to extend the Company's cash runway, it was re-focusing the business on core programs and deprioritizing non-core programs and undertaking a restructuring of the Company including a headcount reduction to be completed in the first quarter of 2023.

The redundancy process was completed in the first quarter of 2023 with a reduction of approximately 25% of global headcount. The redundancy packages to be paid to departing staff comprise a combination of contractual termination benefits, relating to payments that arise from terms of employment contracts and statutory redundancy pay, and one-time employee termination benefits that were provided or enhanced specifically for this redundancy process. Due to the structure of the redundancy scheme and the different employment regulations affecting the Company's U.K. and U.S. employees, some of the expense associated with the one-time employee termination benefits were recognized over the remaining period of employee service to be rendered. Contractual termination benefits and other one-time employee termination benefits were expensed and recognized in the year ended December 31, 2022. All expenses have been recognized in Selling, general and administrative expenses in the Statement of Operations.

The amounts incurred in relation to the redundancy program were as follows:

	<b>Contractual termination benefits</b>	<b>One-time employee termination benefits</b>	<b>Total restructuring costs</b>
Cumulative amount incurred to December 31, 2022	\$ 1,171	\$ 1,114	\$ 2,285
Amount incurred in the year ended December 31, 2023	778	925	1,703
<b>Total amount and cumulative amount incurred to December 31, 2023</b>	<b>\$ 1,949</b>	<b>\$ 2,039</b>	<b>\$ 3,988</b>

No impairment losses were recognised as a result of the restructuring.

*TCR<sup>2</sup> post-acquisition senior leadership severance*

Following the acquisition of TCR<sup>2</sup> Therapeutics Inc. in June 2023 (see Note 18), the Company made most of the former members of TCR<sup>2</sup>'s senior leadership team, comprising the executive officers and most vice presidents, redundant and paid severance packages. The redundancy packages are considered contractual termination benefits as they arise from terms of employment contracts including change-in-control 'dual trigger' provisions, and were comprised of severance and other payments and accelerated vesting of share option awards.

The amounts incurred in relation to these redundancies in the year ended December 31, 2023, are as follows:

	<b>Year ended December 31, 2023</b>
Severance and other cash payments	\$ 5,655

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Accelerated vesting of share-based compensation awards	1,032
<b>Total and cumulative amount incurred</b>	<b>\$ 6,687</b>

The expense associated with the accelerated vesting of share-based compensation awards recognized in Research and development and Selling, general and administrative expenses in the Consolidated Statement of Operations was \$0.2 million and \$0.8 million, respectively.

The table below is a summary of the changes in the liability in the Consolidated Balance Sheet in the year ended December 31, 2024:

	2024	2023
Liability at January 1, 2024 and June 1, 2023	\$ 573	\$ 805
Costs incurred and charged to Research and development expenses	—	1,267
Costs incurred and charged to Selling, general and administrative expenses	—	4,388
Costs paid during the period	(573)	(5,887)
<b>Total liability at December 31</b>	<b>\$ —</b>	<b>\$ 573</b>

The amounts included in liabilities at December 31, 2023 and the cash paid during the period, include amounts relating to accrued payments to these employees for services provided prior to the acquisition of TCR<sup>2</sup> by the Company.

**Note 18 – Business combinations**

On March 6, 2023 the Company announced entry into a definitive agreement under which it would combine with TCR<sup>2</sup> Therapeutics Inc. (“TCR<sup>2</sup>”) in an all-stock transaction to create a preeminent cell therapy company focused on treating solid tumors. TCR<sup>2</sup> is a Boston, Massachusetts-based T-cell therapy company focused on treating solid tumors, with clinical franchises undergoing trials and a preclinical pipeline. The combination provides extensive benefits for clinical development and product delivery supported by complementary technology platforms.

The transaction was approved by the Company’s shareholders and TCR<sup>2</sup> stockholders on May 30, 2023 and the merger became effective on June 1, 2023. The Company issued 357,429,306 shares to TCR<sup>2</sup> stockholders in return for 100% of TCR<sup>2</sup>’s stock. As a result, TCR<sup>2</sup> and all entities within the TCR<sup>2</sup> group, became wholly owned by the Company. Following the completion of the transaction, the former TCR<sup>2</sup> stockholders held approximately 25% of the Company, whereas the Company’s pre-existing shareholders held approximately 75%.

The Company was identified as the acquirer, with TCR<sup>2</sup> as the acquiree, and June 1, 2023 was determined to be the acquisition date.

The consideration transferred for TCR<sup>2</sup> includes the shares issued by the Company to former TCR<sup>2</sup> shareholders, plus the fair value of replacement awards of the Company granted to TCR<sup>2</sup> grant holders attributable to

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pre-combination vesting. The table below summarizes the consideration transferred and the amounts of the assets acquired and liabilities assumed recognized at the acquisition date:

<b>Consideration transferred:</b>	
Fair value of 357,429,306 ordinary shares issued	\$ 60,763
Fair value of replacement options and RSU-style options granted attributable to pre-combination service:	963
<b>Purchase consideration</b>	<b>\$ 61,726</b>
<b>Identifiable assets acquired and liabilities assumed:</b>	
<i>Assets acquired</i>	
Cash and cash equivalents	\$ 43,610
Restricted cash	1,654
Marketable securities - available-for-sale debt securities	39,532
Other current assets and prepaid expenses	6,029
Property, plant and equipment	2,712
Operating lease right-of-use assets	5,145
Intangible assets	58
<b>Total assets acquired</b>	<b>\$ 98,740</b>
<i>Liabilities assumed</i>	
Accounts payable	(6,210)
Accrued expenses and other current liabilities	(4,537)
Operating lease liabilities, current	(1,974)
Operating lease liabilities, non-current	(2,244)
<b>Total liabilities assumed</b>	<b>\$ (14,965)</b>
<b>Net assets acquired and liabilities assumed</b>	<b>\$ 83,775</b>

The fair value of the 357,429,306 ordinary shares issued to TCR<sup>2</sup> stockholders of \$60,763,000 was determined on the basis of the closing market price of \$1.02 (\$0.17 per ordinary share) of the Company's ADSs as of May 31, 2023.

The assets acquired and liabilities assumed were measured based on management's estimates of the fair value as of the acquisition date, excluding leases.

The lease contracts acquired by the Company relate to the rental of office and manufacturing spaces in which TCR<sup>2</sup> was the lessee. The Company retained TCR<sup>2</sup>'s previous classification of acquired leases as operating leases as there were no lease modifications as a result of the combination, with the exception of leases with a remaining lease term of 12 months or less at the acquisition date, for which no assets or liabilities were recognized at the acquisition date. The lease liabilities were measured at the present value of the remaining lease payments as if the leases were a new lease as of June 1, 2023, discounted using the incremental borrowing rate. The right-of-use assets were measured at the same amount as the lease liabilities, with adjustments to reflect favorable or unfavorable terms compared to market terms. No intangible assets were identified in relation to lease contracts acquired.

The table below summarizes the calculation for the gain on bargain purchase, recognized in the Gain on bargain purchase line in the Consolidated Statement of Operations:

**Gain on bargain purchase**

Purchase consideration	\$ (61,726)
Net assets acquired and liabilities assumed	83,775
<b>Gain on bargain purchase</b>	<b>\$ 22,049</b>

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The transaction resulted in a gain on bargain purchase as the purchase consideration included in the agreement on March 6, 2023 comprising Company ADSs was based on a fixed ratio of 1.5117 of the Company's ADSs to be issued for each TCR<sup>2</sup> stock acquired. As the transaction was an all-stock transaction, the value of the consideration was highly sensitive to changes in the Company's ADS price. The price of a Company ADS fell from a closing price of \$1.32 on March 6, 2023 compared to a closing price of \$1.02 on May 31, 2023.

The amount of TCR<sup>2</sup>'s earnings that are included in the Company's Consolidated Statement of Operations for the year ended December 31, 2023 was a loss of \$32,427,000 which excludes the gain on bargain purchase.

The amount of revenue and earnings of the combined entity for the years ended December 31, 2023 and 2022, had the acquisition date been January 1, 2022, are as follows:

	Year ended December 31, 2023	Year ended 2022
Revenue	\$ 60,281	\$ 27,148
Net loss	(177,312)	(301,879)

The supplemental pro forma earnings for the year ended December 31, 2023 were adjusted to exclude the \$22.0 million Gain on bargain purchase, the \$7.3 million of acquisition-related costs recognized by the Company, as detailed below, and the \$9.0 million of acquisition-related costs incurred by TCR<sup>2</sup>. The pro forma earnings for the year ended December 31, 2022 were adjusted to include these gains and losses. The supplemental pro forma earnings for both periods were adjusted to include the impact of replacement options issued, as if these had been issued as of January 1, 2022. Accordingly, the share-based compensation expense recognized by TCR<sup>2</sup> in the year ended December 31, 2022, and the five months ended May 31, 2023, prior to the acquisition by the Company, of \$11.4 million and \$1.0 million, respectively, were excluded from the pro forma earnings.

TCR<sup>2</sup> did not generate revenue in the period from January 1, 2022 to December 31, 2023, as it has no contracts with customers, so there was no impact on the revenue included in the Company's Consolidated Statement of Operations or in the supplemental pro forma revenue and earnings presented above.

The Company incurred the following acquisition-related costs that were recognized as an expense 2023:

	Total acquisition-related costs
Legal, professional and accounting fees	\$ 5,174
Bankers' fees	2,172
<b>Total acquisition-related costs</b>	<b>\$ 7,346</b>

All acquisition-related costs that were recognized as an expense were recognized in Selling, general and administrative expenses in the Consolidated Statement of Operations. No issuance costs were incurred relating to the issuance of shares to TCR<sup>2</sup> stockholders.

**Note 19 – Subsequent events**

On March 24, 2025, Adaptimmune Therapeutics plc (the "Company" and collectively with any Company affiliates that are made party to the Loan Agreement, "Borrower") entered into an amendment ("Amendment") to the Loan and Security Agreement (the "Loan Agreement") between the same Adaptimmune entities and with several banks and other financial institutions or entities from time to time party hereto as lenders (each, a "Lender", and collectively "Lenders") and Hercules Capital, Inc. Under the Amendment the Company will pre-pay \$25.0 million of the loan amount under the Loan Agreement together with certain accrued interest up to the date of such prepayment. The Company will

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also pay an end of term charge on such pre-paid amount of 5.85% as previously provided in the Loan Agreement, such end of term charge being payable upon maturity or repayment of all obligations under the Loan Agreement.

**List of Subsidiaries**

<b><u>Subsidiary Name</u></b>	<b><u>Jurisdiction of Formation</u></b>
Adaptimmune Limited	England and Wales
Adaptimmune LLC	Delaware
Adaptimmune B.V.	The Netherlands
CM Intermediate Sub I, Inc.	Delaware
CM Intermediate Sub II, Inc.	Delaware
TCR <sup>2</sup> Therapeutics Inc.	Delaware
TRUCS Therapeutics Limited	England and Wales

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statement (No. 333-264208) on Form S-3 and registration statements (Nos. 333-275813, 333-233558 and 333-203929) on Form S-8 of our report dated March 24, 2025, with respect to the consolidated financial statements of Adaptimmune Therapeutics plc.

/s/ KPMG LLP

Reading, United Kingdom  
March 24, 2025

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**Form of Certification Required by Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Adrian Rawcliffe, certify that:

1. I have reviewed this annual report on Form 10-K of Adaptimmune Therapeutics plc;
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 24, 2025

/s/ Adrian Rawcliffe  
Adrian Rawcliffe  
*Chief Executive Officer and Director*

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**Form of Certification Required by Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Gavin Wood, certify that:

1. I have reviewed this annual report on Form 10-K of Adaptimmune Therapeutics plc;
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 24, 2025

/s/ Gavin Wood  
Gavin Wood  
*Chief Financial Officer*

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**Section 906 Certificate**

**Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), I, Adrian Rawcliffe, Chief Executive Officer of Adaptimmune Therapeutics plc, a public limited company incorporated under English law (the “Company”), hereby certify, to my knowledge, that:

1. The Company’s annual report on Form 10-K for the year ended December 31, 2024, to which this Certification is attached as Exhibit 32.1 (the “Annual Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 24, 2025

*/s/ Adrian Rawcliffe*  
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Adrian Rawcliffe  
*Chief Executive Officer and Director*

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**Section 906 Certificate**

**Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), I, Gavin Wood, Chief Financial Officer of Adaptimmune Therapeutics plc, a public limited company incorporated under English law (the “Company”), hereby certify, to my knowledge, that:

1. The Company’s annual report on Form 10-K for the year ended December 31, 2024, to which this Certification is attached as Exhibit 32.2 (the “Annual Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 24, 2025

/s/ Gavin Wood  
Gavin Wood  
*Chief Financial Officer*

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