# 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	S EXCHANGE ACT OF 1934
	For the fiscal year ended	December 31, 2019	
	OR		
☐ TRANSITION REPORT PURSUA	ANT TO SECTION 13 OR 1	5(d) OF THE SECURI	TIES EXCHANGE ACT OF 1934
	For the transition period f	rom to	
	Commission File Nur	nber 001-37368	
ADAF	PTIMMUNE THE (Exact name of Registrant as s		PLC
England and Wales	•		Not Applicable
(State or other jurisdiction of incorporation	or organization)	(I.R.S.	Employer Identification No.)
60 Jubilee Avenue, Milton P Abingdon, Oxfordshire OX14 United Kingdom (Address of principal executive o	4RX	(Registrant's te	(44) 1235 430000 elephone number, including area code)
(	Securities registered pursuant to	, 3	
<b>Title of each class</b> American Depositary Shares, each representing 6 O Shares, par value £0.001 per share	Trading Sy Ordinary ADAI		Name of each exchange on which registered The Nasdaq Global Select Market
	Securities registered pursuant to <b>None</b>	Section 12(g) of the Act:	
Indicate by check mark if the registrant is a well-kn	own seasoned issuer, as defined in R	ule 405 of the Securities Act.	□ Yes ⊠ No
Indicate by check mark if the registrant is not require	red 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 12 months (or for such shorter period that the registrant $w$			Securities Exchange Act of 1934 during the preceding ling requirements for the past 90 days. $\boxtimes$ Yes $\square$ No
Indicate by check mark whether the registrant has so ( $\S 232.405$ of this chapter) during the preceding 12 month			
Indicate by check mark if disclosure of delinquent f to the best of registrant's knowledge, in definitive proxy of			pter) is not contained herein, and will not be contained, is Form 10-K or any amendment to this Form 10-K. 🛭
Indicate by check mark whether the registrant is a la company. See the definitions of "large accelerated filer,"			
Large accelerated filer $\square$ Accelerated	filer $\boxtimes$	Non-accelerated filer $\Box$	Smaller reporting company $\boxtimes$ Emerging growth company $\square$
If an emerging growth company, indicate by check accounting standards provided pursuant to Section 13(a) of		to use the extended transition p	period for complying with any new or revised financial
Indicate by check mark whether the registrant is a sl	hell company (as defined in Rule 12b	o-2 of the Act). $\square$ Yes $\boxtimes$ No	
As of June 28, 2019, the last business day of the reg value $\pounds 0.001$ per share, held by non-affiliates was approx		cond fiscal quarter, the aggrega	te market value of the registrant's ordinary shares, par
As of February 26, 2020 the number of outstanding	ordinary shares, par value £0.001 per	r share, of the Registrant is 780	),451,790.
	DOCUMENTS INCORPORA	TED BY REFERENCE	
The following documents (or parts thereof) are inco Report on Form 10-K is incorporated from our definitive fiscal year ended December 31, 2019.			ertain information required by Part III of this Annual ommission not later than 120 days after the close of our

#### 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" and "SPEAR" are registered trademarks of Adaptimmune.

#### **Information Regarding Forward-Looking Statements**

This Annual Report contains forward-looking statements that are based on our current expectations, assumptions, estimates and projections about us and our industry. All statements other than statements of historical fact in this Annual Report are forward-looking statements.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- our ability to successfully advance our ADP-A2M4 (MAGE-A4), ADP-A2M4CD8 (MAGE-A4CD8) and ADP-A2AFP (AFP) products through clinical development and the timing within which we can recruit patients and treat patients in all of our clinical trials;
- our ability to fund our operations and continue as a going concern;
- our ability to successfully and reproducibly manufacture SPEAR T-cells and other cell therapies in order to meet patient demand;
- our ability to further develop our commercial manufacturing process for our SPEAR T-cells and other cell
  therapies, transfer such commercial process to third party contract manufacturers, if required, and for such third
  party contract manufacturers or ourselves to manufacture SPEAR T-cells to the quality and on the timescales
  we require;
- our ability to successfully advance our SPEAR T-cell technology platform, to improve the safety and effectiveness of our existing SPEAR T-cell candidates, to identify and develop new cell therapies and to submit Investigational New Drug Applications, or INDs, for new cell therapies;
- the rate and degree of market acceptance of cell therapy generally, and of our particular cell therapies including our SPEAR T-cells;
- government regulation and approval, including, but not limited to, the expected regulatory approval timelines
  for our SPEAR T-cells and the level of pricing and reimbursement for our SPEAR T-cells, if approved for
  marketing;
- our ability to successfully commercialize any products;
- the existence of any third-party patents preventing further development of any of our cell therapies, including, any inability to obtain appropriate third party licenses, or enforcement of patents against us or our collaborators;
- our ability to obtain granted patents covering our cell therapies and to enforce such patents against third parties;
- volatility in equity markets in general, and in the biopharmaceutical sector in particular and our ability to maintain compliance with the Nasdaq Global Select Market closing bid price requirement;

- fluctuations in the price of materials and bought-in components;
- the scope and timing of performance of our ongoing collaborations with GlaxoSmithKline ("GSK") and with Universal Cells Inc., a wholly owned subsidiary of Astellas Pharma, Inc. ("Universal Cells");
- our relationships with suppliers, contract manufacturing organizations or CROs and other third-party providers
  including fluctuations in the price of materials and services, ability to obtain reagents particularly where such
  reagents are only available from a single source, and performance of third party providers;
- increased competition from other companies in the biotechnology and pharmaceutical industries including where such competition impacts ability to recruit patients into clinical trials;
- claims for personal injury or death arising from the use of our cell therapies;
- our ability to attract and retain qualified personnel; and
- additional factors that are not known to us at this time.

Additional factors that could cause actual results, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results to differ materially include, but are not limited to, those discussed under "Risk Factors" in Part I, Item 1A in this Annual Report and in our other filings with the Securities and Exchange Commission (the "SEC"). Additional risks that we may currently deem immaterial or that are not presently known to us could also cause the forward-looking events discussed in this Annual Report not to occur. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar words are intended to identify estimates and forward-looking statements. Estimates and forward-looking statements speak only at the date they were made, and we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Our future results may differ materially from those expressed in these estimates and forward-looking statements. In light of the risks and uncertainties described above, the estimates and forward-looking statements discussed in this Annual Report might not occur, and our future results and our performance may differ materially from those expressed in these forward-looking statements due to, inclusive of, but not limited to, the factors mentioned above. Because of these uncertainties, you should not make any investment decision based on these estimates and forward-looking statements.

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#### Item 1. Business

#### Overview

We are a clinical-stage biopharmaceutical company focused on providing novel cell therapies to people with cancer. We are a leader in the development of T-cell therapies for solid tumors.

Our proprietary SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables us to identify cancer targets, find and genetically engineer T-cell receptors ("TCRs") against those targets, and produce therapeutic candidates ("SPEAR T-cells") for administration to patients. Using our affinity engineered TCRs, we aim to become the first company to have a TCR T-cell approved for the treatment of a solid tumor indication. We have clinical trials ongoing with our whollyowned ADP-A2M4, ADP-A2M4CD8 (the "SURPASS" trial), each targeting the MAGE-A4 antigen, and ADP-A2AFP SPEAR T-cells targeting the AFP cancer antigen in a total of ten solid tumor types including non-small cell lung cancer ("NSCLC"), head and neck cancer, ovarian, urothelial, melanoma, hepatocellular, esophageal, gastric, synovial sarcoma and myxoid round cell liposarcoma ("MRCLS") cancers. Current data provide an encouraging demonstration of the potential of our SPEAR T-cell platform across multiple targets and a range of solid tumors:

ADP-A2M4—Multiple Indications: A Phase 1 clinical trial is ongoing in urothelial, melanoma, head and neck, ovarian, NSCLC, esophageal and gastric cancers, synovial sarcoma and MRCLS. RECIST responses have been reported in patients with synovial sarcoma and head and neck cancer. A radiation sub-study under this Phase 1 clinical trial is continuing with a partial response being seen in the first patient treated. A Phase 2 clinical trial has been initiated in synovial sarcoma and MRCLS indications. In addition, planning is ongoing for initiation of a clinical trial combining ADP-A2M4 with a PD-1 / PD-L1 pathway inhibitor in 2020.

**ADP-A2AFP** - **Hepatocellular Carcinoma**: We continue dosing patients in our Phase 1, open-label, dose-escalation study designed to evaluate the safety and anti-tumor activity of our alpha fetoprotein ("AFP") therapeutic candidate for the treatment of hepatocellular carcinoma, or HCC. Patients are being treated with target doses of 5 billion SPEAR T-cells (range 1.2 to 6 billion) and the first patient treated at this target dose achieved a partial response.

**ADP-A2M4CD8—SURPASS Trial:** Enrollment has started in a Phase 1 trial for a next generation SPEAR T-cell, ADP-A2M4CD8. This next generation SPEAR T-cell utilizes the same engineered T-cell receptor as ADP-A2M4, but with the addition of a CD8α homodimer. The addition of the CD8α homodimer has been shown in vitro to increase cytokine release and SPEAR T-cell potency. A partial response was reported in the first patient treated.

A fourth SPEAR T-cell, the NY-ESO SPEAR T-cell, was transitioned to GlaxoSmithKline ("GSK") in 2018, following GSK's exercise of its option to obtain an exclusive global license to the NY-ESO SPEAR T-cell program in September 2017.

We have our own manufacturing facility in the United States that manufactures SPEAR T-cells to treat patients across a broad range of solid tumors. We also have our own dedicated vector manufacturing in the United Kingdom which, together with our US manufacturing facility, will enable us to continue improving the effectiveness and patient experience associated with our cell therapies.

We continue to develop our preclinical pipeline of new cell therapies, including SPEAR T-cells, CAR-Ts and novel HLA independent TCR ("HiT") therapies to both new targets and to existing targets towards further HLA types. As part of this research and development, we are developing next generation and combination approaches to enhance our cell therapies. These are being developed internally and in collaboration with third parties including Alpine Immune Sciences ("Alpine") and Noile-Immune Biotech Inc. ("Noile-Immune").

We have also developed an allogeneic platform for "off-the-shelf" cell immunotherapies, including CAR-T and TCR T-cells. On January 13, 2020, we entered into an agreement with Universal Cells Inc. ("Universal Cells"), a whollyowned subsidiary of Astellas Pharma Inc., for the co-development and co-commercialization of stem-cell derived allogeneic CAR-T and TCR T-cell therapies. The agreement covers the co-development and co-commercialization of up

to three T-cell therapies and combines Universal Cells' donor cell gene editing platform and our stem-cell derived allogeneic T-cell platform. Universal Cells also has the right to select two targets and develop allogeneic cell therapy candidates independently. This agreement follows collaboration with Universal Cells Inc. since 2015 on the development of gene-edited induced pluripotent stem cells (iPSCs), for which Adaptimmune has the exclusive rights to develop and commercialize resulting T-cell therapy products using its proprietary process for generating T-cells from iPSCs.

#### **Business Strategy**

Building on our leadership position with T-cell therapies in solid tumor indications, our strategic objective is to be a world leader in designing and delivering cell therapies that transform the lives of people with cancer. We have an ambition to have the first TCR T-cell therapy approved for a solid tumor indication. In order to achieve our objectives, we are focused on the following:

**Progressing our T-cell therapies through research and development.** We continue to advance our T-cell therapies through development including our SPEAR T-cells which are in clinical trials in multiple tumor indications. In research, we are developing new cell therapies which we aim to advance into clinical trials, to treat different indications and patient populations, on completion of pre-clinical testing. For example, we are generating SPEAR T-cells, CAR-T and HLA independent TCR T-cells ("HiT") against multiple tumor indications.

**Advancing our cell therapies towards commercialization.** Depending on data from Phase 1 clinical trials, we will rapidly progress clinical candidates through clinical trials and towards commercialization. For example, our ADP-A2M4 therapy is in a Phase 2 clinical trial, called SPEARHEAD-1, in North America, Canada, UK and the European Union for the treatment of patients with synovial sarcoma and MRCLS. Depending on the data obtained, we aim to progress quickly towards commercialization of ADP-A2M4 in these indications. Planning for commercialization of this therapy is in progress.

**Continuing to develop 'off-the-shelf' cell immunotherapies.** We are progressing with our allogeneic (or 'off the shelf') platform for the development of cell therapies, both internally and in collaboration with partners. We believe, using an "off-the-shelf" product will be transformative for patients. The platform is being developed to facilitate manufacture of multiple cell therapy products including TCR T-cells, CAR-T cells and other cell therapies.

Continuing to develop next-generation and combination approaches to further enhance our cell therapies. We continue to evaluate and work to understand the tumor micro-environment and the mechanism of action of our cell therapies in order to enhance them. We will continue to progress these approaches internally and through multiple external collaborations including those with Alpine and Noile-Immune. These approaches include next generation approaches like ADP-A2M4CD8, currently in the SURPASS Phase 1 trial, for which the aim is to increase cytokine release and SPEAR T-cell potency, as well as combination approaches like our intended combination trial with a PD-1/PD-L1 pathway inhibitor.

Continuing to improve our manufacturing and patient supply processes to optimize how we deliver our cell therapies to patients. We are continuing to enhance our T-cell and vector manufacturing processes at all stages of the process. Improvements may enhance the end cell therapy product and reduce overall turnaround time, all of which will enable us to treat patients quicker and more effectively.

**Building an integrated cell therapy company capable of delivering our cell therapies to patients.** We continue to build and develop our capabilities as an integrated cell therapy company across all activities required for researching, developing, manufacturing, supplying and commercializing our cell therapies. Having a fully integrated capability across all these areas enables flexibility and control.

**Expanding our intellectual property portfolio.** We intend to continue building on our technology platform, comprising intellectual property, proprietary methods and know-how in the field of cell therapies. These assets form the foundation for our ability to strengthen our product pipeline and to defend and expand our position as a leader in the field of cell therapies.

#### **Our Cell Therapies**

#### 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, or 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 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.

#### 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 must be expressed primarily only on the cancer cells of interest and with expression in normal non-cancerous tissue only where a risk to the patient would be deemed acceptable. Careful validation and identification of targets is important to ensuring 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 target identification platform is focused on three approaches. First, we are using our platform to validate cancer testis antigens, for example the MAGE-A4 antigen. Second, we are using our platform to identify non-cancer testis antigens which are closely related to a specific disease indication, for example the AFP antigen. Finally, we are identifying intracellular targets in the context of different HLA types or extracellular cell surface targets for HLA-independent constructs ensuring that we can address a broader patient population either across multiple HLA types or without HLA restriction, respectively.

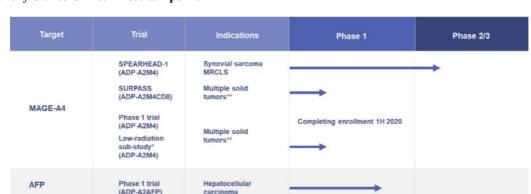
#### **Engineering of T-cells**

Following identification of a suitable target peptide, we identify TCRs or other cell therapy receptors (for example CAR) that are capable of binding to that target peptide or protein. We then engineer and optimize those identified receptors to enhance and optimize 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 cell therapy then undergoes extensive preclinical safety testing prior to administration to patients. Our SPEAR T-cell platform technology which utilizes affinity engineered TCRs enables us to develop a pipeline of targets and TCR therapeutic candidates that we believe may be effective in a variety of cancer types that are unresponsive to currently available and experimental therapies. We have three wholly owned SPEAR T-cells currently in clinical trials (ADP-A2M4CD8, ADP-A2M4 and ADP-A2AFP) and a pipeline of SPEAR T-cells and other cell therapies in development, including SPEAR T-cells directed to peptides expressed in the context of different HLA-types.

Other cell therapies being developed include CAR T-cells where a CAR (Chimeric Antigen Receptor) is engineered to recognize proteins expressed on the surface of the cancer cells to enable the T-cells to be directed to and to recognize those cancer cells and HLA-independent TCRs (HiTs) which are able to recognize cell surface antigens expressed by cancer cells independently of HLA.

#### **Administration to Patients**

The current process for treating a patient with our cell therapies involves extracting the patient's T-cells and then combining the extracted cells with our delivery system containing the gene for our engineered cell therapy, through a process known as transduction. Our delivery system uses a type of self-inactivating (SIN) virus, known as SIN-lentivirus, to transduce the patient's T-cells ("lentiviral vector"). The transduced T-cells are then expanded and infused back into the patient. When these T-cells encounter a recognized peptide or protein, they multiply and initiate the destruction of the targeted cancer cells.



#### **Our Wholly Owned Clinical Product Pipeline**

- \* Site specific protocol amendment with MD Anderson Cancer Center
- \*\* Bladder, Melanoma, Head & Neck, Ovarian, NSCLC, Esophageal, Gastric, Synovial sarcoma, MRCLS (myxoid/round cell liposarcoma)

*ADP-A2M4—Multiple Indications:* Clinical trials are ongoing with our ADP-A2M4 SPEAR T-cell in multiple indications. In addition, planning is ongoing for initiation of a clinical trial combining ADP-A2M4 with a PD-1 / PD-L1 pathway inhibitor in 2020.

- A Phase 1 clinical trial in multiple tumor indications, namely urothelial, melanoma, head and neck, ovarian, NSCLC, esophageal and gastric cancers, synovial sarcoma and MRCLS completed enrollment in early 2020.
  - O As of October 23, 2019, data from 14 evaluable patients with synovial sarcoma treated in the expansion phase of this trial demonstrated an overall response rate of 50% (including both confirmed and unconfirmed partial responses (PRs)). 13 out of 14 evaluable patients had evidence of disease control (with best overall responses of partial response (7 patients) or stable disease (6 patients)). A clinical update was provided at the Connective Tissue Oncology Society in November 2019.
  - 9 Beyond synovial sarcoma tumor shrinkage has been observed in patients with melanoma and ovarian cancers and a partial response was reported in a head and neck cancer patient.
- A Phase 2 clinical trial has been initiated in synovial sarcoma and MRCLS ("Spearhead -1"). The trial will take place at sites in the United States, Canada and Europe. The trial will include up to 60 patients at a selected dose of up to 10 billion transduced ADP-A2M4 SPEAR T-cells. Primary responses will be assessed by overall response rate by RECIST v1.1 ("Response Evaluation Criteria In Solid Tumors v1.1"). The lymphodepletion regimen will be fludarabine (30 mg/m²/day) for 4 days and cyclophosphamide (600 mg/m²/day) for 3 days.
- A radiation sub-study under the Phase 1 clinical trial is continuing at the MD Anderson Cancer Center. The sub-study will treat up to 10 patients and has a primary endpoint of safety, with RECIST v1.1 responses being a secondary endpoint. The radiation is a low dose radiation and is administered to lesions or isocenters prior to lymphodepletion.

**ADP-A2AFP** - **Hepatocellular Carcinoma**: We continue dosing patients in our Phase 1, open-label, dose-escalation study designed to evaluate the safety and anti-tumor activity of our alpha fetoprotein ("AFP") therapeutic candidate for the treatment of hepatocellular carcinoma, or HCC. The trial is open in the United States, United Kingdom

and the European Union. Patients are now enrolling in Cohort 3 and are being treated with target doses of 5 billion SPEAR T-cells (range 1.2 to 6 billion). The first patient treated in this cohort had a confirmed PR (decrease of 100% in target lesions). Most adverse events to date are consistent with those typically experienced by cancer patients undergoing cytotoxic chemotherapy or other cancer immunotherapies.

ADP-A2M4CD8— $SURPASS\ Trial$ : Enrollment has started in a Phase 1 trial for a next generation SPEAR T-cell, ADP-A2M4CD8. This next generation SPEAR T-cell utilizes the same engineered T-cell receptor as ADP-A2M4, but with the addition of a CD8α homodimer. The addition of the CD8α homodimer has been shown in vitro to increase cytokine release and SPEAR T-cell potency. The SURPASS trial will enroll up to 30 patients across multiple solid tumor indications. Similar to our other trials, the SURPASS trial will include dose escalation. Unlike the other trials, the stagger between patients will be shorter and the starting dose in the first cohort will be 0.8 to 1.2 billion SPEAR T-cells, instead of 100 million SPEAR T-cells, as was previously the case. Each dose cohort will enroll three patients and can be expanded to six patients if a dose limiting toxicity occurs. After dose escalation is complete, there is an Expansion Phase with doses up to 10 billion cells. The lymphodepletion regimen will be fludarabine (30 mg/m²/day) for 4 days and cyclophosphamide (600 mg/m²/day) for 3 days. A partial response was reported in the first patient treated.

*ADP-A2M10:* Two Phase 1 clinical trials were conducted with ADP-A2M10 for the treatment of (i) NSCLC, and (ii) urothelial, melanoma and head and neck cancers in the United States, Canada, the United Kingdom and Spain. Enrollment in these trials closed as planned in 2019.

#### NY-ESO SPEAR T-cell Therapy (transitioned to GSK)

A fourth SPEAR T-cell, the NY-ESO SPEAR T-cell, was transitioned to GlaxoSmithKline ("GSK") in 2018, following GSK's exercise of its option to obtain an exclusive global license to the NY-ESO SPEAR T-cell program in September 2017. GSK has assumed full responsibility for all development, manufacturing and commercialization activities for the NY-ESO SPEAR T-cell, including progression of this SPEAR T-cell into further clinical trials. Under the ongoing Collaboration and License Agreement with GSK, a third target program remains ongoing. GSK is currently entitled to nominate a fourth target program and, upon satisfying other conditions, may have the right to nominate a fifth program under the GSK Collaboration and License Agreement, in each case excluding our ongoing wholly-owned development programs.

#### Preclinical candidates and next generation technology

We continue to progress development of new SPEAR T-cells and other cell therapies including HLA-independent TCRs (HiTs) and CAR-Ts directed to new targets and to targets expressed in the context of HLA-types other than HLA-A2. As part of our preclinical development we also have multiple development programs ongoing both internally and with third party collaborators to develop various approaches to enhance our cell therapy products.

#### Allogeneic iPSC platform

We are looking to develop our SPEAR, CAR and HiT candidates in T-cells that are universally applicable to all patients by developing gene-edited inducible pluripotent stem cells (iPSC) differentiated to T-cells by our in-house proprietary process. These "off-the shelf cells" are being developed to overcome the current limitation of autologous therapies that need to be manufactured specifically for each patient and donor-derived T-cells which may need repeated infusions. The enhanced T-cell technology being developed involves selective engineering for the removal of certain cell surface proteins (for example, Human Leukocyte Antigen ("HLA") molecules) and the addition of our receptor candidates,

without the use of nucleases, to develop these T-cell products. If successful, this will enable us to treat our patients with an off-the-shelf cell therapy product

#### **Manufacturing Platform Development**

#### **Manufacturing Capability**

We have our own SPEAR T-cell manufacturing capability at the Navy Yard in Philadelphia, Pennsylvania which is capable of manufacturing all of our wholly owned assets across a range of solid tumors. The Navy Yard facility is currently able to produce SPEAR T-cell product for up to 10 patients per month. With further investment the facility could treat over 1,000 patients per year. We also have the ability to use third party contract manufacturing if required to increase capacity.

We have our own dedicated vector manufacturing capability in the United Kingdom, within the Catapult Cell and Gene Therapy Manufacturing Centre in Stevenage, which is now able to produce vector for our Phase 1 clinical trials. The first batch of GMP vector was completed in Q4 of 2019 and is pending final quality release testing. Control of our own end-to-end manufacturing process (including vector, T-cell and analytical quality control testing) enables us to improve and further develop our processes for manufacture of our cell therapies. We continue to work with our third-party vector manufacturer for supply of vectors to support our ongoing clinical trials.

#### **Manufacturing Improvements**

We have the goal of reducing the time between apheresis of a patient and return of affinity enhanced SPEAR T-cells back to the patient. We have made a number of changes to our current SPEAR T-cell manufacturing process and are continuing to make changes. We are now able to manufacture SPEAR T-cells with a 25-day processing time and we continue to optimize further. The combination of integrated manufacturing capability with continuing process development enables us to continue to be a leader in cell therapy manufacture.

#### **Core Alliances and Collaborations**

#### Universal Cells Co-development Collaboration Agreement

On January 13, 2020, Adaptimmune Therapeutics plc (the "Company" or "Adaptimmune") entered into a Codevelopment and Co-commercialization agreement ("Agreement") with Universal Cells, Inc., a wholly-owned subsidiary of Astellas Pharma Inc ("Universal Cells").

Under the Agreement the parties will agree on up to three targets and will co-develop T-cell therapies directed to those targets pursuant to an agreed research plan. For each target, Universal Cells will fund co-development up until completion of a Phase 1 trial for products directed to such target. Upon completion of the Phase 1 trial for a product, Universal Cells and Adaptimmune will elect whether to progress with co-development and co-commercialization of such product, or to allow the other party to pursue the candidate independently.

If the parties progress with co-development and co-commercialization of a product, then each party will grant the other party a co-exclusive license to co-develop and co-commercialize such product in the field of T-cell therapy. If a product is developed solely by one party, then the other party will grant to the continuing party an exclusive license to develop and commercialize such product in the field of T-cell therapy.

In addition, Universal Cells is also granted the right to develop, independently of Adaptimmune, allogeneic T-cell therapy candidates directed to two targets selected by Universal Cells. Universal Cells will have sole rights to develop and commercialize products directed against such products.

Under the terms of the agreement, Adaptimmune may receive up to \$897.5 million in payments, including:

An upfront payment of \$50 million.

- Development milestones of up to \$73.75 million for each co-developed and co-commercialized product
- Development milestones of up to \$147.5 million per product and up to \$110 million in sales milestones for products developed unilaterally by Universal Cells.

In addition, Adaptimmune will receive research funding of up to \$7.5 million per year and tiered royalties on net sales in the mid-single to mid-teen digits.

Under the terms of the Agreement and in consideration for rights under certain contributed Universal Cells technology for a product unilaterally developed by Adaptimmune, Universal Cells may receive up to \$552.5 million, including up to \$147.5 million in milestone payments per product and up to \$110 million in sales milestones for products developed unilaterally by Adaptimmune. In addition, Universal Cells will receive tiered royalties on net sales in the mid-single to midteen digits.

To the extent that Universal Cells and Adaptimmune co-develop and co-commercialize any product, the parties will share equally all worldwide costs and profits. Further details governing the parties' co-commercialization will be articulated in a product-specific commercialization agreement.

Either party can terminate the Agreement in the event of material breach or insolvency of the other party. Universal Cells can terminate the Agreement for convenience in its entirety or partly in relation to any targets and products directed to such targets. Adaptimmune can terminate the Agreement for convenience in relation to any target it is unilaterally developing and to products directed to such target.

In addition to the Agreement, the parties have also made amendments to the pre-existing agreement between Universal Cells, Inc. and Adaptimmune which was announced on December 1, 2015. The pre-existing agreement relates to the use of Universal Cells gene editing and HLA-editing technology in the context of the development of our own allogeneic T-cell therapies. The amendments relate primarily to changes to the development plan agreed between the parties and the pre-existing agreement has been amended and re-stated as at January 13, 2020 as a result of the changes agreed. Adaptimmune retains exclusive rights in the T-cell field under the agreement.

#### **GSK Collaboration and License Agreement**

We entered into the GSK Collaboration and License Agreement regarding the development, manufacture and commercialization of TCR therapeutic candidates in May 2014. The collaboration is for up to five programs. The first program was the NY-ESO SPEAR T-cell program, in relation to which GSK has now exercised its option to take an exclusive license. The second program related to development of a SPEAR T-cell to a peptide derived from the PRAME antigen. This program has now completed. The third target program with GSK remains ongoing.

Under the terms of the GSK Collaboration and License Agreement, the Company may be entitled to:

- development milestones of up to £18 million (\$23 million) per product and HLA-type for the NY-ESO Program and up to £21.5 million (\$27.3 million) per product and HLA-type for other programs (including the third target program);
- regulatory milestones of up to £36 million (\$45.7 million) per product and HLA-type for the NY-ESO program and up to £40 million (\$50.8 million) per product and HLA-type for other programs (including the third target program); and
- commercialization milestones upon the first commercial sale of a product of up to £70.5 million (\$89.5 million) per product and HLA-type for the NY-ESO Program and up to £80 million (\$101.5 million) per product and HLA-type for other programs (including the third target program).

The development and regulatory milestones are per product milestones and are dependent on achievement of certain obligations, the nature of the product being developed, stage of development of product, territory in which an obligation is achieved and type of indication or indications in relation to which the product is being developed. In addition, for any program, multiple products may be developed in the context of different HLA-types. As of December 31, 2019, we had achieved development milestones of \$69.6 million.

For other programs (including the third target program) under the GSK Collaboration and License Agreement, an option fee is also payable of up to £6 million (\$7.6 million) on exercise of the option by GSK, after which GSK is responsible for all development expenses.

For any product that is commercialized by GSK, the Company may receive tiered sales milestones up to £200 million (\$253.8 million) per product and HLA-type and mid-single to low double-digit royalties on worldwide net sales of the applicable product. Royalties are payable while there is a jointly owned or solely owned valid patent claim covering the SPEAR T-cell in the country in which the relevant SPEAR T-cell is being sold and, in each case, for a minimum of 10 years from first commercial sale of the relevant TCR therapeutic. Sales milestones also apply once any TCR therapeutic covered by the GSK Collaboration and License Agreement is on the market.

On September 7, 2017, we announced that GSK had exercised its exclusive option for the NY-ESO SPEAR T-cell program. Transition of the program to GSK occurred during 2018. GSK has now assumed full responsibility for the NY-ESO SPEAR T-cell program including any ongoing clinical trials. As a result of the option exercise, Adaptimmune received £48 million (approximately \$61 million) from GSK over the course of the transition period. This included development milestones of £18 million (approximately \$23 million) and an option payment of £30 million (approximately \$38 million), which also allows GSK to nominate two additional targets following completion of the transition. Successful continuation of development and subsequent commercialization of NY-ESO would trigger additional payments for development milestones, tiered sales milestones, and mid-single to low double-digit royalties on worldwide net sales.

Upon nomination of the third target program by GSK, we have granted to GSK an exclusive option to the nominated target which can be exercised up to four months after approval of an IND application in relation to a TCR therapeutic candidate directed against the nominated target. We are responsible for taking the third target program through preclinical testing and up to IND application filing. GSK is responsible for the IND filing itself should the preclinical testing and development be favorable.

Two other targets may be nominated by GSK at specified times under the GSK Collaboration and License Agreement, excluding any wholly-owned research programs already in progress by us. Upon nomination by GSK of any of these two additional targets, we will grant to GSK an exclusive option on each target, which can be exercised up to four months after approval of an IND application in relation to a TCR therapeutic candidate directed against the nominated target. Nomination also triggers the start of a collaboration program to develop the relevant TCR therapeutic candidate directed to the nominated target peptide.

Following exercise of any option (including the options for the NY-ESO SPEAR T-cell and third target programs), we will grant to (and have granted in relation to the NY-ESO SPEAR T-cell) GSK an exclusive worldwide license under intellectual property rights specific to the SPEAR T-cell developed under the relevant collaboration programs. GSK will, at its own expense, be fully responsible for all further development and commercialization of the relevant T-cell candidates. The licenses do not include a right for GSK to develop alternative affinity-enhanced TCRs using our intellectual property rights or to develop other TCR therapeutic candidates directed to different target peptides. Under the agreement, we are also prohibited from independently developing or commercializing T-cell therapeutics directed at the targets subject to outstanding options granted to GSK.

The GSK Collaboration and License Agreement is effective until all payment obligations expire, including any ongoing royalty payments due in relation to GSK's sale of any covered TCR therapeutic candidates. The agreement can also be terminated on a collaboration program-by-collaboration program basis by GSK for lack of feasibility or inability to meet certain agreed requirements. Both parties have rights to terminate the agreement for material breach upon 60 days' written notice or immediately upon insolvency of the other party. GSK has additional rights to terminate either the agreement or any specific license or collaboration program upon 60 days' written notice to us. Additional payments may be due to us as a result of such termination, and where we continue any development of any TCR therapeutic candidate resulting from a terminated collaboration program, depending on the stage of development, royalties may be payable to GSK at a mid-single-digit percentage rate of net sales. We also have rights to terminate any license where GSK ceases development or withdraws any licensed SPEAR T-cells in specified circumstances.

#### Preclinical and Clinical Collaborations

We have third party collaborations in place with Noile-Immune, Alpine Immune Sciences and Bellicum.

With Alpine, we are collaborating to develop next-generation SPEAR T-cell products that incorporate Alpine's secreted and transmembrane immunomodulatory protein technology. The collaboration agreement was announced in May 2019, and we believe that the Alpine technology will complement our existing internal next generation technology and enhance anti-tumor potential through engagement of further rapid and flexible immunomodulatory mechanisms. In the Noile-Immune collaboration, announced in August 2019, we will co-develop next-generation SPEAR T-cell products, incorporating Noile-Immune's PRIME (proliferation inducing and migration enhancing) technology, based upon co-expression of IL-7 and CCL19. Under the Bellicum collaboration we are evaluating Bellicum's GoTCR technology (inducible MyD88/CD40 co-stimulation, or iMC) with our SPEAR T-cells for the potential to create enhanced T-cell therapeutics.

We also have a strategic alliance agreement with the MD Anderson Cancer Center which covers both the conduct of certain clinical trials for our SPEAR T-cell therapies and also certain pre-clinical research work.

#### **Intellectual Property**

We actively 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 SPEAR T-cells 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 claiming priority from the initial application(s) and then application for patent grant in, for example, the United States, Europe (including major European territories), Japan, Australia, New Zealand, India and Canada. 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 preclinical candidates.

As of December 31, 2019 we owned or jointly owned approximately 143 granted patents (of which 20 are U.S. issued patents) and 172 pending patent applications (of which 37 are U.S. National patent applications).

#### **Product Patent families**

**ADP-A2AFP** - We own a patent application covering the composition of matter of ADP-A2AFP. The patent application claims are primarily directed to the engineered TCR therapeutic candidate, the use of the ADP-A2AFP therapy and in particular the amino acid substitutions required for such engineered TCR therapeutic candidate. An initial priority patent application was filed in the UKIPO and a patent application under the applicable Patent Co-operation Treaty has since been filed claiming priority from that United Kingdom patent application. National applications have been filed in all commercially relevant territories and claims have been allowed in Europe and the US. We expect any composition of matter patents within this family, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2034 (worldwide, excluding possible patent term extensions).

*ADP-A2M4* - We own 3 patent applications 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. Patent applications have also been filed in relation to the use of ADP-A2M4 in combination with PD-L1/PD-1 inhibitors. The initial priority patent applications were filed in the UKIPO and patent applications under the applicable Patent Cooperation Treaty have since been filed claiming priority from that United Kingdom patent application. National applications have been filed in all commercially relevant territories. We expect any composition of matter patents within this family, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2037-2039 (worldwide, excluding possible patent term extensions).

**ADP-A2M4CD8** – We own a patent application covering the composition of matter of ADP-A2M4CD8 and other related TCR T-cell therapies. The patent application claims are directed to the engineered TCR therapeutic candidate in combination with the CD8 next generation technology. The initial priority patent applications were filed in the UKIPO and patent applications under the applicable Patent Co-operation Treaty have since been filed claiming priority from that United Kingdom patent application. We expect any composition of matter patents within this family, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2037-2039 (worldwide, excluding possible patent term extensions).

*ADP-A2M10* - We own patent applications covering the composition of matter of ADP-A2M10. The patent application claims are directed to the engineered TCR therapeutic candidate and in particular the amino acid substitutions required for such engineered TCR therapeutic candidate. An initial priority patent application was filed in the United Kingdom Intellectual Property Office ("UKIPO") and a patent application under the applicable Patent Co-operation Treaty has since been filed claiming priority from that United Kingdom patent application. National applications have been filed in all commercially relevant territories. We expect any composition of matter patents within this family, if issued, and if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, to expire in 2035 (worldwide, excluding possible patent term extensions).

We also have product patent applications filed in relation to our new cell therapy candidates including candidates to new targets and our new HLA-independent T-cell therapies (HiTs).

#### Platform Technology

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 SPEAR TCRs and other cell therapies. These are owned jointly with Immunocore Limited, with whom we have historically had a shared development history.

**Novel targets** - We have filed 29 patent applications under the Patent Cooperation Treaty which cover peptides expressed on the tumor cell surface and the TCRs which recognize them. The applications as filed cover 872 peptides from 63 different target proteins. National applications have been filed in all commercially relevant territories.

*TCR libraries* - We have filed 10 patent applications which cover large libraries of TCR genes which we have generated and the method of their generation: these act as proprietary sources for screening for TCRs, which are the starting points for affinity engineering into clinical candidates. National applications have been filed in all commercially relevant territories

*Di-sulphide bond* - patents directed to the di-sulphide bond stabilization technique required to solubilize TCRs for isolation, characterization and validation have been issued in major territories including Australia, Canada, China, major European territories (including the United Kingdom, France, Germany, Spain and Italy), India, Hong Kong, Japan, the United States and South Africa and are expected to expire beginning in 2022.

*Phage Display technology* - Patents have also been granted in relation to our phage display approach for receptor development and are expected to expire beginning in 2023 if the appropriate maintenance, renewal, annuity, or other governmental fees are paid. The priority patent application was filed in 2002 and patents are now granted in the United States, Australia, Canada, China, major European territories (including the United Kingdom, France, Germany, Spain and Italy), Japan, South Africa, India, Norway and New Zealand.

We also have an issued patent directed to a method for increasing the affinity of given TCRs to a target peptide. (expected to expire in 2025) and patent applications directed to decreasing off-target reactivity and selection for the affinity-enhanced TCRs.

#### **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 United States and allowed in Europe. Further patent applications have been filed on the manufacturing and quality control of our products.

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

We have 4 patent applications filed covering a range of next generation technology approaches and/or combination approaches.

#### Allogeneic iPSC platform approaches

We have filed a number of patent applications covering our proprietary iPSC stem cell differentiation technology which enables the differentiation of stem cells into T-cells which can then be administered to patients. The patent applications are primarily directed to the various stages required for the differentiation of the iPSC stem cells into different cell line types including NK cells, NKT cells, macrophages, dendritic cells, alphabeta T-cells, and gammadelta T-cells.

#### Third-Party Intellectual Property Rights

We have a non-exclusive license from ThermoFisher Inc. under certain of its intellectual property rights covering its Dynabeads® CD3/CD28 technology. This technology is used in our manufacturing process to isolate, activate and expand patient T-cells. We also have a supply agreement which runs until December 31, 2025 under which we are required to purchase CD3/CD28 magnetic bead product. See "Risk Factors—Risks Related to Our Reliance Upon Third Parties—We rely heavily on ThermoFisher and the technology we license from them."

Third-party patents do exist that purport to cover some of our current lentiviral vectors/systems or our process for manufacture. However, the majority of these patents will expire prior to any commercial supply by us of any cell therapies and we do not currently require a license. Whether licenses are required under any remaining third-party patents or other third-party patents depends on what steps we take going forward in relation to our lentiviral transduction process and manufacturing process including our allogeneic manufacturing and differentiation process. We may, however, need to negotiate a license under any remaining third party patents or develop alternative strategies for dealing with any remaining 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, intense competition, a strong emphasis on proprietary products and intellectual property. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any SPEAR T-cells that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

Immunotherapy is an active area of research and a number of immune-related products have been identified in recent years that are alleged to modulate the immune system. Many of these products utilize dendritic cells, a form of immune cell that presents cancer target peptides to T cells and that can in turn result in T-cell activation. More recently, bispecific antibodies and checkpoint inhibitors (for instance PD-1/PD-L1 antibodies) have been identified as having utility in the treatment of cancer. Bi-specific antibodies commonly target both the cancer target, or in some cases peptide-HLA complex (so-called "TCR mimics"), and link to the CD3 molecule of T cells, thus bringing both cancer cells and T cells into close proximity to maximize the chance of T-cell binding and hence an immune response to the cancer cells. Checkpoint inhibitors, on the other hand work by targeting receptors that inhibit T-cell effectiveness and proliferation and essentially activate T cells. Other immunotherapies that are being actively investigated include: antibody-drug complexes, TCR-mimic antibodies, oncolytic viruses, cancer vaccines. A variety of cell-based autologous and allogeneic ("off-the-shelf") approaches are also being researched and developed, including but not limited to: CAR-T cell, TCR T-cell, GammaDelta T-cell, CAR-NK cell, NKT cell and CTL.

- CAR-T in hematological malignancies: Engineered T-cell therapeutics have been identified using antibody recognition systems engineered into T cells, so-called CAR-T cells. A number of targets in hematological malignancies have been well characterized including, but not limited to: BCMA, CD4, CD5, CD19, CD22, CD20, CD33, CD38, CD70, CS1 and CD123. Two CD-19 directed CAR-T cell products have been approved by the U.S. Food and Drug Administration ("FDA") Kymriah™ (tisagenlecleucel) and Yescarta™ (axicabtagene ciloleucel) as well as by the European Medicines Agency (EMA) in the European Union. More recently, Kymriah™ has been approved by the MHLW in Japan. A number of companies and academic institutions are developing CAR-T cell products including but not limited to Allogene Therapeutics, Arcellx, Atara Bio, Autolus, Baylor College of Medicine, bluebird bio, CASI Pharmaceuticals, Celyad, Celgene (now part of Bristol-Myers Squibb), Cellectis, CRISPR Therapeutics, Fate Therapeutics, Janssen (JNJ with Nanjing Legend), Juno Therapeutics (a Bristol-Myers Squibb company), Kite Pharma (Gilead), Linea Rx, Mustang Bio, Novartis, Precigen, Refuge Biotechnologies Inc., Servier, Sorrento Therapeutics, Xenetic Biosciences, Xyphos (a wholly-owned subsidiary of Astellas) and Ziopharm Oncology.
- CAR-T in solid tumors: In addition to hematological malignancies, there are a growing number of pharmaceutical, biotechnology, and academic institutions researching and developing autologous and allogeneic CAR-T therapies in the solid tumor setting. These CAR-T cell therapies are at a variety of stages of preclinical and clinical development, as well as directed towards a broad target spectrum, including but not limited to: DLL3, EGFR, GD2, HER-2, IL13rα2, Lewis Y, L1-CAM, Mesothelin, MUC16, PSCA, PSMA and ROR1. Competitors include but are not limited to: Allogene Therapeutics, Amgen, Atara Bio, Aurora Biopharma, Baylor College of Medicine, Cell Medica, Bellicum, BioNTech, Carisma Therapeutics (formerly CARMA Therapeutics), Carsgen, Celgene (now part of Bristol-Myers Squibb; with Obsidian Therapeutics) Cellectis Therapeutics, Celyad, CRISPR Therapeutics, Endocyte (a Novartis Company), Fate Therapeutics, Formula Therapeutics, Fred Hutchinson Cancer Research Center, Helix BioPharma, Juno Therapeutics (a Bristol-Myers Squibb company), Lyell Immunopharma (with GSK), MaxCyte, Memorial Sloan Kettering Cancer Center, Minerva Biotechnologies, Mustang bio, OncoSec Immunotherapies, Oncternal Therapeutics, Poseida Therapeutics, Precigen, Senti Biosciences, Sorrento Therapeutics, Symvivo, Targazyme, Tmunity, Xyphos (a wholly-owned subsidiary of Astellas).
- CARs & TCR-mimics targeting peptide-HLA complexes: Most CAR-T therapies in development are directed towards suitable antigen targets. Another area of development is the creation of CAR-T that selectively binds to the peptide-HLA (pHLA) complex (the natural binding site for endogenous TCR). Furthermore, competitors are also looking at pHLA antibodies or TCR mimic antibodies that can either be engineered in T-cells or developed as standalone antibody therapies in cancer indications (both hematologic malignancies and solid tumors). Targets of such pHLA CAR-T or TCR mimic antibodies include: AFP, CD19, BCMA, NY-ESO-1, p53 and WT1. A number of pharmaceutical, biotechnology, and academic institutions are researching and developing CARs & TCRmimics targeting the peptide-HLA complex, including but not limited to: Adicet Bio / Regeneron, Altor Bioscience, Cancer Research Technology/CRUK, Eureka Therapeutics, Gritstone Oncology, MorphoSys, Xencor and Ziopharm Oncology.
- TCR T-cells: TCR T-cells are being developed by competitors that are directed towards a multitude of targets including: AFP, CD20, HPV-16 E6/E7, KRAS, MAGE-A1, MAGE-A3, MAGE A3/A6, MART1, NRAS, NY-ESO-1, p53, PRAME, TGFβRII frameshift antigen WT1, as well as personalized neoantigens. Juno Therapeutics (a Bristol-Myers Squibb company) has developed an engineered TCR therapeutic candidate where

the end TCR is purported to have enhanced affinity through stem-cell selection. Juno's candidate JTCR016 (WT1specific TCR), in collaboration with Fred Hutchinson Cancer Research Center and the National Cancer Institute (NCI), is currently undergoing a Phase 1/2 trial in NSCLC and mesothelioma setting as well as a separate Phase 1/2 in AML. Medigene AG has reported development of a PRAME TCR therapeutic candidate (MDG1011), which has begun a Phase 1/2 clinical investigation in AML, MM and myelodysplastic syndromes. In addition to Juno there is a growing number of TCR companies that are adopting approaches to TCR affinity enhancement, for example Axis Therapeutics, Takara, Takara Bio, Fred Hutchinson Cancer Centre and Immatics. In addition other TCR-focused competitors include, but are not limited to: 3T, Adaptive Biotechnologies (with Genentech), AgenTus, Atreca, Baylor College, Bellicum, BioNTech (with Eli Lilly), bluebird bio, BlueSphere bio, Captain T cell, Celgene (now part of Bristol-Myers Squibb; with Immatics), Cellular Biomedicine Group Inc, Cell Medica Ltd, Cytovant Sciences, Ervaxx, GigaMune, GSK, HighPass Bio (an Elevate bio company), Immunocellular Therapeutics, Immunocore, Intellia Therapeutics, Inc. (with Ospedale San Raffaele), Juno Therapeutics (a Bristol-Myers Squibb company), Kiromic, Kite Pharma (Gilead), Lion TCR LTD, MD Anderson Cancer Center, MediGene AG, NCI, Neon Therapeutics, PACT Pharma, Parker Institute, Refuge Biotechnologies Inc., Roswell Park Cancer Institute, Scancell (with BioNTech), Tactiva Therapeutics, Takara Bio Inc, Takeda (T-CIRA), TCR Cure, T-Cure, TCR x immunotherapies, T-Knife, Tmunity, TScan Therapeutics, University of Leiden, Zelluna (with Oslo University Hospital) and Ziopharm Oncology.

There are a number of different approaches being developed for allogeneic or "off-the-shelf" immunotherapy products including stem-cell derived products, HLA-matched products, healthy-donor derived products and use of cells with no or limited HLA type (for example GammaDelta T-cell, or NK cells). Competitors include Allogene Therapeutics (with Notch Therapeutics), Century Therapeutics (with FujiFilm Cellular Dynamics), City of Hope (with Mustang Bio), Editas (through Juno/Celgene/Bristol Myers Squibb), Fate Therapeutics, Takeda (in collaboration with CiRA), Thyas, Editas, UCLA and T-CiRA.

In addition to adoptive cell therapy approaches aforementioned, our competitors are also investigating other cell-based approaches, including the potential of GammaDelta T-cell, CAR-Macrophages, CAR-NK cell, NK cell, NKT cell, CTLs, TILs, Marrow-infiltrating lymphocytes (MILs), Multi-tumor-associated antigen (TAA)-specific T-cells and virus-specific T-cells either preclinically or in a clinical setting (both hematologic malignancies and solid tumors). In this space there are a number of potential competitors, including, but not limited to: Achilles Therapeutics, Adicet Bio, Arsenal bio, Atara Bio, Aurora BioPharma, Cell Medica, Cellular Biomedicine Group Inc, CytomX, Celgene (now part of Bristol-Myers Squibb), Fate Therapeutics, Fortress Biotech, Gadeta (with Kite Pharma), Gamma Delta Therapeutics (with Takeda), Gamida cell, Genocea, Glycostem Therapeutics, iCell Gene Therapeutics, Immatics, Iovance Biotherapeutics (formerly Lion Bio), KSQ Therapeutics, MD Anderson Cancer Center, Multimmune, NantKwest, NexImmune, Nkarta, Sorrento Therapeutics, Marker Therapeutics, Tessa Therapeutics, TC Biopharm (with Bluebird Bio), Torque Therapeutics, Unum Therapeutics, WindMIL Therapeutics and Ziopharm Oncology.

#### **Government Regulation and Product Approvals**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, 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 United States 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.

The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgogement

of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice ("DOJ"), or other governmental entities.

#### FDA Approval Process

In the United States, therapeutic products, including drugs, biologics, and medical devices are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 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. Some biological products are subject to regulation under the FDC Act. Most biological products are approved for marketing under provisions of the Public Health Service Act ("PHSA") via a Biologics License Application ("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, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an 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 drug 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 tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not communicated deficiencies with the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order 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. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. An 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.

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 drug or 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 relationship of the drug or biologic and to provide adequate information for the labeling of the product.

In most cases, the FDA requires two adequate and well-controlled clinical trials to demonstrate the efficacy of the biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in some instances 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 impossible.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing, compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls as well as proposed labeling for the product. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee, currently exceeding \$2,335,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding \$110,000 per product and \$569,000 per establishment. These fees are typically increased annually.

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 it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologic products are reviewed within 10 months of the date the FDA files the BLA; most applications for priority review biologics are reviewed within six months of the date the FDA files the BLA. Priority review can be applied to a biologic that the FDA determines 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 review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel biologic products, or biologic products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice cGMP is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe, pure, potent and effective in the indication studied.

After the FDA evaluates the BLA, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, 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.

An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. 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. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, may require submission and FDA approval of a BLA supplement before the change can be implemented. A BLA supplement for a new indication may require clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

#### FDA Guidance Governing Gene Therapy Products

The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper preclinical assessment of gene therapies; the chemistry, manufacturing, and controls information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND application or BLA; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high.

#### Expedited Pathways

The FDA is required to facilitate the development, and expedite the review, of biologics that are intended for the treatment of a serious or life- threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. These expedited programs include fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation.

#### Fast Track Designation

Under the fast track program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Benefits such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

#### Accelerated Approval

Under the fast track program and FDA's accelerated approval regulations, the FDA may approve a 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.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A biologic candidate approved on this basis is subject to

rigorous post- marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval trials, or confirm a clinical benefit during post-marketing trials, will allow the FDA to withdraw the biologic from the market on an expedited basis. All promotional materials for biologic candidates approved under accelerated regulations are subject to prior review by the FDA.

#### Breakthrough Therapy Designation

The FDA is also required to expedite the development and review of the application for approval of biological products that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. Breakthrough Therapy Designation has all of the benefits of Fast Track designation as well as additional benefits such as FDA organizational commitment and intensive FDA guidance.

The FDA may also award RMAT designation (Regenerative Medicine Advanced Therapy designation) to regenerative medicine products. An RMAT designation is similar to breakthrough therapy designation and includes increased opportunities to meet with FDA officials and early meetings to discuss potential surrogate or intermediate endpoints. RMAT designation is available to regenerative medicine therapies where the therapy is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and the preliminary clinical evidence indicates that the therapy has the potential to address unmet medical needs for the disease or condition.

#### Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biological products intended to treat a rare disease or condition, generally a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a product available in the United States 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. The first BLA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market a biological product containing the same active moiety for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes 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. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA user fee.

#### Disclosure of Clinical Trial Information

Sponsors of human clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

#### Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or efficacy supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. 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, or BPCA, a sponsor that qualifies for "pediatric exclusivity" is entitled to an additional six months of market exclusivity if it complies with a Written Request, or WR, issued by FDA for pediatric studies. The sponsor may apply to FDA to issue a WR. Pediatric exclusivity may apply to patent rights and to FDA regulatory exclusivity and operates by adding six months of exclusivity on to the end of the latest-expiring form of exclusivity. To qualify for pediatric exclusivity, at least one of those rights must still be currently in force at the time FDA approves the pediatric studies.

#### 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 United States 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, or 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, a biological product may be deemed biosimilar to an FDA-approved biological product or reference biological product upon a showing that there are no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity generally must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary waives a required element. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. On March 6, 2015, the FDA approved the first biosimilar product under the BPCIA. As of January 2019, the FDA had approved a total of 17 biosimilars, and seven of these had been launched into the U.S. market.

Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which is still being evaluated by the FDA. Controversy over the appropriate manner of naming biosimilars has caused delay as well, with FDA currently calling for biosimilar names to have a random four-letter suffix appended to the name of the reference compound to which they refer. In addition, complexities of the regulatory provisions of the BPCIA, as well as the patent litigation provisions in the statute and accompanying litigation, have also led to a relatively slow pace of biosimilar approvals. FDA is taking steps to address these issues, most recently issuing the Biosimilars Action Plan, or BAP, to increase the speed and efficiency of biosimilar approvals and usage in the clinical setting.

A reference biologic is granted 12 years of marketing exclusivity from the time of first licensure of the reference product, and in addition no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. 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 biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen 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's application has been approved if a patent lawsuit is ongoing within the 42-month period.

#### Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry- sponsored scientific and educational activities and promotional activities involving the internet. Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

#### FDA Regulation of Companion Diagnostics

If safe and effective use of a therapeutic product depends on an *in vitro* diagnostic, then 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 and by the FDA's Center for Devices and Radiological Health.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It 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. PMA applications are subject to an application fee, which exceeds \$250,000 for most PMAs. 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. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, 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.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

#### 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. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Act, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

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. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

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. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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.

#### Other Federal and State Regulatory Requirements

The Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that implements a statutory requirement under the Healthcare Reform Act that requires applicable manufacturers of drugs, devices, biologicals, or medical supplies that are covered under Medicare, Medicaid, or the Children's Health Insurance Program, or CHIP, to begin collecting and reporting annually information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. Manufacturers had to begin collecting information in 2013, with the first reports due in 2014. On September 30, 2014, CMS posted the first round of data in searchable form on a public website. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual physicians in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical trials and their outcomes. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

#### Europe and Rest of the World Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions both due to our location and the fact that we are engaging in clinical programs outside of the United States and will want to obtain worldwide regulatory approval for our TCR therapeutic candidates. In particular we have clinical trials ongoing in the United Kingdom and Spain and will be subject to regulations relating to performance of those clinical trials and manufacture and supply of our SPEAR T-cells and patient materials in the United Kingdom and Spain. Prior to supplying any TCR therapeutic candidate in any country or starting any clinical trials in any country outside of the United States we must obtain the requisite approvals from regulatory authorities in such countries. The existence of a United States 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 TCR therapeutic candidates. In the European Union, 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 authority(ies).

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 United States

In order to market any product outside of the United States, 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 European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union 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 European Union 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. 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.

To obtain marketing approval of a product under European Union 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 European Union 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.

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 European Union, 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. The Commission's decision is in accordance with the CHMP's assessment except in very rare cases.

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. 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).

#### **Legal Proceedings and Related Matters**

From time to time, we may be party to litigation that arises in the ordinary course of our business. We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our results of operations, financial condition or cash flows.

#### **Employees**

As of December 31, 2019, we had 400 employees. Of these employees, 315 were in research and development (including in manufacturing and operations, and quality control and quality assurance) and 85 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 represented by a labor union. We believe our employee relations are good.

#### **Available Information**

Access to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed with or furnished to the SEC, may be obtained through the investor section of our website at www.adaptimmune.com as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. 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 by reference. Our filings with the SEC may be accessed through the SEC's website at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

#### **Corporate Information**

Adaptimmune Therapeutics plc was incorporated on December 3, 2014 and is a public limited company incorporated under the laws of England and Wales. Our registered and principal executive offices are located at 60 Jubilee Avenue, Milton Park, Abingdon, Oxfordshire OX14 4RX, United Kingdom, our general telephone number is (+44) 1235 430000 and our corporate website address is www.adaptimmune.com. Our website and the information contained on or accessible through our website are not part of this document. Our agent for service of process in the United States is Adaptimmune LLC, located at 351 Rouse Boulevard, The Navy Yard, Philadelphia PA 19112, United States.

#### 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 significant 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.

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

We are a clinical-stage biopharmaceutical company with no commercial products and prediction of future performance is very difficult.

We are a clinical-stage biopharmaceutical company focused on novel cancer immunotherapy products. We have no products or therapeutics approved for commercial sale and have not generated any revenue from product supplies or royalties. Our therapeutic candidates, in particular our SPEAR T-cells, are new and largely unproven. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Our inability to address these risks successfully would have a materially adverse effect on our business and prospects.

#### 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 SPEAR T-cells and other cell therapies (including the NY-ESO SPEAR T-cell), including engaging in activities to manufacture and supply our SPEAR T-cells for clinical trials in compliance with current good manufacturing practice, or cGMP, conducting clinical trials of our SPEAR T-cells, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product supplies or royalties. Based on our current plans, we do not expect to generate product or royalty revenues unless and until we obtain marketing approval for, and commercialize, any of our SPEAR T-cells or other cell therapies.

For the years ended December 31, 2019, 2018, 2017, 2016 and the six months ended December 31, 2015 and the year ended June 30, 2015, we incurred net losses of \$137.2 million, \$95.5 million, \$70.1 million, \$71.6 million, \$23.0 million and \$22.1 million, respectively. As of December 31, 2019, we had accumulated losses of \$455.7 million. 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 product candidates is difficult to estimate given the novel nature of our cell therapies and their un-proven route to market. Our profitability is dependent upon the successful development, approval, and commercialization of our SPEAR T-cells and other cell therapies, further development of the NY-ESO SPEAR T-cells by GSK (given the NY-ESO program has now been transitioned to GSK), achieving GSK milestones (for both the NY-ESO program, the third SPEAR T-cell programs under the agreement with Universal Cells Inc. and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional cash or alternative funding.

Although our financial statements have been prepared on a going concern basis, if we fail to obtain additional financing in future, this may raise substantial doubt about our ability to continue as a going concern in future reporting periods

As of December 31, 2019, the Company had cash and cash equivalents of \$50.4 million, marketable securities of \$39.1 million, and stockholders' equity of \$123.6 million. During the year ended December 31, 2019, the Company incurred a net loss of \$137.2 million, used cash of \$112.5 million in its operating activities, and generated revenues of \$1.1 million. The Company has incurred net losses in most periods since inception and it expects to incur operating losses in future periods. On January 13, 2020, the Company entered into a co-development and co-commercialization agreement with Astellas Pharma, Inc. (the "Astellas Collaboration Agreement"). The Company received an upfront payment of \$50.0 million in January 2020 under the agreement and is entitled to receive research funding of up to \$7.5 million per year. Additional milestones are possible under the agreement, but these are dependent on the success of the development and commercialization of research and products. In addition, on January 24, 2020, the Company closed an underwritten public offering of 21,000,000 American Depository Shares (ADSs) which, together with the full exercise by the underwriters on February 7, 2020, of their option to purchase an additional 3,150,000 ADSs, generated net proceeds of approximately \$89.8 million. We believe that our Total Liquidity, combined with the upfront payment and

the recently completed public offering of ADSs described above, will be sufficient to fund our operations, based upon our currently anticipated research and development activities and planned capital spending, into the second half of 2021.

Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued.

We have never generated any revenue from sales of our cell therapies and our ability to generate revenue from sales of our cell therapies and become profitable depends significantly on our success in a number of factors.

We have no cell therapies approved for commercial sale, have not generated any revenue from sales of our cell therapies, and do not anticipate generating any revenue from sales of our cell therapies until sometime after we receive regulatory approval, if at all, for the commercial sale of a cell therapy. We intend to fund future operations through milestone payments under our collaboration and license agreements with GSK and Universal Cells Inc. and through additional equity financings or other third party collaborations. Our ability to generate revenue and achieve profitability depends on our success in many factors, including:

- completing preclinical development and advancing our SPEAR T-cells and other cell therapies to clinic;
- delivering on the clinical development strategy for our SPEAR T-cells and other cell therapies;
- progressing our clinical trials within predicted timeframes and without any substantial delays, for example as
  may be caused by delays in patient recruitment, regulatory requirements to hold or suspend any clinical trials or
  delays in obtaining approvals required to conduct clinical trials;
- demonstrating a favorable benefit (efficacy parameters): risk (safety) for our SPEAR T-cells and the NY-ESO SPEAR T-cell that translate into a differentiated product of value for patients;
- obtaining data from clinical trials which are ongoing for SPEAR T-cells other than the NY-ESO SPEAR T-cell;
- obtaining regulatory approvals and marketing authorizations for our SPEAR T-cells and the NY-ESO SPEAR
   T-cell for which we or our collaborator complete clinical trials;
- developing sustainable and scalable manufacturing and supply processes for our cell therapies, including
  establishing and maintaining commercially viable supply relationships with third parties and establishing our
  own commercial manufacturing capabilities and infrastructure;
- developing a reliable and commercially viable/cost effective commercial manufacturing process to enable commercial supply of our cell therapies;
- launching and commercializing therapies for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance, pricing and reimbursement of our SPEAR T-cells and other cell therapies as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new cell therapies including new SPEAR T-cells;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

attracting, hiring and retaining qualified personnel.

Even if one or more of the SPEAR T-cells is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved SPEAR T-cell. Our expenses could increase beyond expectations if the FDA or any other regulatory agency requires changes to our manufacturing processes or assays, or for us to perform preclinical programs and clinical or other types of trials in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more SPEAR T-cells, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the SPEAR T-cell, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales or supplies of such SPEAR T-cells, even if approved. If we are not able to generate revenue from the sale of any approved SPEAR T-cells, we may never become profitable.

### If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our SPEAR T-cells.

Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the development of our SPEAR T-cells, including future clinical trials. If we receive approval for any of our SPEAR T-cells, we will require significant additional amounts in order to launch and commercialize these therapeutic candidates.

As of December 31, 2019, we had \$50.4 million of cash and cash equivalents and \$39.1 million of marketable securities. We expect to use these funds to advance and accelerate the clinical development of our SPEAR T-cells, to further develop and enhance our manufacturing capabilities and secure a commercially viable manufacturing platform for all of our SPEAR T-cells, to advance additional SPEAR T-cells into preclinical testing and progress such SPEAR T-cells through to clinical trials as quickly as possible and to fund working capital, including for other general corporate purposes. Changing circumstances beyond our control, including changes to the scope and timing of the programs under the GSK collaboration (for example, nomination of further targets by GSK or changes to the third target program) or data seen in any of our clinical trials may cause us to increase our spending significantly faster than we currently anticipate. We will require additional capital for the further development and commercialization of our SPEAR T-cells in accordance with currently planned operations.

We cannot be certain that additional funding will be available 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 may have to significantly delay, scale back or discontinue the development or commercialization of our SPEAR T-cells, cell therapies or other research and development initiatives. 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 SPEAR T-cells 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 SPEAR T-cells in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our American Depositary Shares, or ADSs, to decline.

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

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 your rights as a shareholder. The incurrence of 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.

#### Risks Related to the Development of Our SPEAR T-cells

Our business is highly dependent on our wholly owned SPEAR T-cell candidates including ADP-A2M4, ADP-A2M4CD8, and ADP-A2AFP, which will require significant additional clinical testing before we can seek regulatory approval and begin commercialization of any of our SPEAR T-cells.

There is no guarantee that any SPEAR T-cells will achieve regulatory approval or proceed to the next stage of clinical programs. The process for obtaining marketing approval for any candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval, if at all.

There is no guarantee that the results obtained in current clinical trials for our ADP-A2M4, ADP-A2M4CD8, and ADP-A2AFP SPEAR T-cells will be sufficient for us to plan one or more pivotal clinical trials and obtain regulatory approval or marketing authorization. Negative results in any SPEAR T-cell clinical program (including in any program using the NY-ESO SPEAR T-cell) may also impact our ability to obtain regulatory approval for other SPEAR T-cells or other cell therapies, either at all or within anticipated timeframes because, although the SPEAR T-cell may target a different cancer peptide, the underlying technology platform and other aspects of our clinical programs are the same or substantially similar for all of our SPEAR T-cells and may be the same for certain other 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 SPEAR T-cells or related cell therapies.

The data produced in our ongoing clinical trials is at an early stage and future data may not show responses in patients treated or support continued progression of any of our therapies through development.

The patient response data that has been reported in our ADP-A2M4 trials (other than for synovial sarcoma), ADP-A2AFP trials and ADP-A2M4CD8 trials represents data from individual patients within each study at the applicable dosing level. As such, the data is initial data and we cannot know at this stage whether any patient who has seen a response will continue to respond favorably to our therapy or that any response will persist. In addition, given the data is initial single patient data, there is no assurance 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 is required in order to determine whether any specific SPEAR T-cell is able to be further developed, proceed to the next stage of clinical program and in particular whether any SPEAR T-cell will achieve regulatory approval

We plan to provide further data updates as and when the applicable data is believed to be sufficiently mature. We do not, however, intend to update patient response information on a frequent basis or as and when we obtain further patient information. Given the nature of T-cell therapies and the time taken to observe patient responses to our SPEAR T-cells, we cannot provide any assurance that further data updates will be provided frequently or that such data updates will be available at any particular time.

Negative results in any SPEAR T-cell clinical program may also impact our ability to obtain regulatory approval for other SPEAR T-cells, either at all or within anticipated timeframes because, although the SPEAR T-cell may target a different cancer peptide, the underlying technology platform and other aspects of our clinical programs are the same or substantially similar for all of our SPEAR T-cells. 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 SPEAR T-cells.

We may not be able to submit INDs, or the foreign equivalent outside of the United States, to commence additional clinical trials for cell therapies on the timeframes we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed with planned clinical trials.

Progression of new cell therapies, including other SPEAR T-cells, into clinical trials is inherently risky and dependent on the results obtained in preclinical programs, the results of other clinical programs and results of third-party

programs that utilize common components, such as production of the lentiviral vector lot used for production and administration of our SPEAR T-cell. If results are not available when expected or problems are identified during any cell therapy development, we may experience significant delays in development of pipeline products and in existing clinical programs, which may impact our ability to receive regulatory approval. This may also impact our ability to achieve certain financial milestones and the expected timeframes to market any of our SPEAR T-cells. Failure to submit further IND or the foreign equivalent and commence additional clinical programs will significantly limit our opportunity to generate revenue.

There is no guarantee that the FDA, or any other regulatory authority, will approve any IND (or equivalent application) for any of our future cell therapies, or for new indications for our SPEAR T-cells already in clinical trials, or that amendments to existing protocols will not be required. For example, we amended the protocols for all of our pending and ongoing ADP-A2M4 and ADP-A2M10 clinical trials in response to reported serious adverse events of prolonged serious pancytopenia in our clinical trials for ADP-A2M4 and ADP-A2M10 in two patients treated with the highest lymphodepletion regimen. Such protocol amendments may delay our clinical trials, may require changes or resubmission of our INDs, or may result or be related to a halt in our planned or contemplated clinical trials.

We are continuing to expand our clinical trial footprint in Europe. 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 required additional testing to be conducted in order for approval to be obtained.

In the USA, some institutional review boards, or IRBs, have requested that the Sponsor obtain Investigational Device Exemptions (IDE) from the FDA for the validated clinical trial assay being used to select patients. This has delayed the initiation of some sites and limited the ability to obtain high risk biopsies until an IDE has been granted. We plan to proactively seek IDEs for our SPEAR T-cell and other cell therapy assays where appropriate.

### Our cell therapies being developed may have potentially fatal cross-reactivity to other peptides or protein sequences within the human body.

One of our prior SPEAR T-cells, designed to target an HLA-1 restricted MAGE-A3 cancer-specific peptide, recognized another unrelated peptide from a protein called TITIN, expressed within normal cardiac and other muscle tissues in patients. As a result of this cross-reactivity to the TITIN protein in the heart, two patients died during our MAGE-A3 clinical program, the program was put on pause, then formally placed on hold by the FDA, after which we terminated the program. We subsequently developed a preclinical safety testing program that identifies potential cross-reactivity risks but there may be gaps or other problems detected in the testing program at a later date. Even with the use of this testing program, there can be no guarantee that the FDA will permit us to begin clinical trials of any additional SPEAR T-cells other than those for which INDs already exist or that other off-target cross-reactivity will not be identified or present in any patient group. Failure to develop an effective preclinical safety testing program will prevent or delay clinical trials of any SPEAR T-cell. Detection of any cross-reactivity will halt or delay any ongoing clinical trials for any SPEAR T-cell and prevent or delay regulatory approval. Given that the underlying technology platform, manufacturing process and development process is similar or has shared elements for all of our cell therapies, issues pertaining to cross-reactivity for one SPEAR T-cell may impact our ability or our collaborator's ability to obtain regulatory approval for other cell therapies undergoing development and clinical trials, which would significantly harm our business, prospects, financial condition and results of operations.

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 SPEAR T-cells binds to peptides presented by HLAs other than the HLA type for which the relevant TCR was developed. We have developed a preclinical screening process to identify allo-reactivity risk, however it is not possible to identify all potential risks or to screen all HLA types. Where any allo-reactivity risk is identified, patients with the allo-reactive alleles will be excluded from the trial. Any allo-reactivity or other cross-reactivity that impacts patient safety could materially impact our ability to advance our SPEAR T-cells into clinical trials or to proceed to market approval and commercialization. In addition, there is no guarantee that exclusion of patients with the identified allo-reactive allele will successfully eliminate the risk

of allo-reactivity, and serious side effects for patients may still exist. Given that the underlying technology platform, manufacturing process and development process are similar or shared for all of our cell therapies, issues pertaining to allo-reactivity for one SPEAR T-cell may impact our ability or our collaborator's ability to obtain regulatory approval for other cell therapies undergoing development and clinical trials, which would significantly harm our business, prospects, financial condition and results of operations.

Our T-cell therapy, which is a type of cell therapy that uses gene therapy technology, represents a novel approach to cancer treatment that could result in heightened regulatory scrutiny, delays in clinical development, or delays in our or our collaborator's ability to achieve regulatory approval or commercialization of cell therapies including our SPEAR T-cells.

Use of any of our cell therapies to treat a patient requires the use of gene therapy technology, which involves combining a patient's T-cells with our lentiviral delivery vector or other vector containing the gene for our affinity-enhanced engineered receptor or TCR. This is a novel treatment approach that carries inherent development risks. We are therefore constantly evaluating and adapting our cell therapies following the results obtained during development work and the clinical programs. Further development, characterization and evaluation may be required, depending on the results obtained, in particular where such results 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. Consequently, this may have a material impact on our ability to receive milestone payments and/or generate revenue from our SPEAR T-cells or other cell therapies.

In addition, given the novelty of our cell therapies, the end users and medical personnel require a substantial amount of education and training in their administration of cell therapies. Regulatory authorities have very limited experience with commercial engineered cell therapies and SPEAR T-cells for the treatment of cancer. As a result, regulators may be more risk adverse or require substantial dialogue and education as part of the normal regulatory approval process for each stage of development of any cell therapy. To date, only a limited number of gene therapy products have been approved in the United States and European Union. 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.

Additionally, because our technology involves the genetic modification of patient cells *ex-vivo* using a viral vector, we are subject to many of the challenges and risks of gene therapy, including the following challenges:

- 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 United States in 2003. In those studies, insertional oncogenesis resulted in patients developing leukemia following treatment with the relevant gene therapy, with one patient dying. As a result of the data from those studies, the FDA temporarily halted gene therapy trials in the United States. The previous trials involved modification of stem cells rather than T-cells and utilized a murine gamma-retroviral vector rather than a lentiviral vector. We cannot guarantee that insertional oncogenesis resulting from administration of our SPEAR T-cells or other cell therapies will not occur.
- 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. We may need to adopt such an observation period for our therapeutic candidates; however, the FDA does not require that the tracking be complete prior to its review of the Biologics License Application, or BLA.

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 European Union. These additional processes may delay or impede the initiation of a clinical trial.

If adverse events of the type described above were to occur, further advancement of our clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations. In addition, heightened regulatory scrutiny of gene therapy product candidates may result in delays and increased costs in bringing a product candidate to market, if at all. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate revenue in the future.

In addition, results seen in third party clinical trials using other cell therapy products, for example CAR-T products, or in clinical trials conducted by our collaborators may impact on the further advancement of our clinical trials.

Results seen in third party clinical trials using products that are also used in our combination clinical trials, may impact on the further advancement of our similar clinical trials or clinical trials of our collaborators where similar product types are used.

T-cell therapy is a novel approach to cancer treatment that creates significant increased risk in terms of side-effect profile, ability to satisfy regulatory requirements associated with clinical trials and the long- term viability of administered SPEAR T-cells or other cell therapies.

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 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.

We are aware that certain patients do not respond to our SPEAR T-cells and that other patients may relapse or cease to present the peptide being targeted by such SPEAR T-cells. 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 or our collaborator's ability to conduct clinical trials, to obtain regulatory approvals, if at all, and to successfully commercialize any SPEAR T-cell.

Clinical trials using our SPEAR T-cell therapeutics are still in the early stages, and it is difficult to predict the results that will be obtained by us or our collaborator in ongoing clinical trials or the next phase or phases of any clinical program. It is also difficult to predict the way in which SPEAR T-cells or other cell therapies will interact with third-party products used in combination clinical trials. Any undesirable side effects seen in combination trials may affect our ability or our collaborator's ability to continue with and obtain regulatory approval for any combination therapy and may also impact our or our collaborator's ability to continue with and obtain regulatory approval for the cell therapies alone.

There is a significant risk at each stage of any clinical program that serious adverse events or low efficacy, as well as less favorable benefit:risk profiles, will prevent any SPEAR T-cell program from proceeding further or will result in those programs being suspended or placed on hold (whether voluntarily or as a result of a regulatory authority requirement). For example, there is a risk that the target (or similar) peptide to which any SPEAR T-cell is directed may be present in both patients' cancer cells and other non-cancer cells and tissues. Should this be the case, patients may suffer a range of side effects associated with the SPEAR 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.

Serious adverse events seen with other immunotherapy products, such as the severe 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 SPEAR 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.

As of January 10, 2020, for ADP-A2AFP, ADP-A2M4, and ADP-A2M10:

- The adverse events occurring in >10% of subjects treated with ADP-A2AFP and considered by investigators to be at least possibly related to ADP-A2AFP include neutropenia/neutrophil count decreased, leukopenia/white blood cell count decreased, lymphopenia/lymphocyte count decreased, thrombocytopenia/platelet count decreased, hypoalbuminemia, febrile neutropenia, pyrexia, increase in alanine aminotransferase, increase in aspartate aminotransferase, increase in alkaline phosphatase, diarrhea, vomiting, CRS, dyspepsia, hyperkalemia, lethargy, cognitive disorder, hypotension, pain in extremity, and muscular weakness. Serious adverse events reported with ADP-A2AFP whether considered related to the SPEAR T-cells or not include CRS, bile duct obstruction and abdominal pain.
- The adverse events occurring in >10% of subjects treated with ADP-A2M4 and considered by investigators to be at least possibly related to ADP-A2M4 include neutropenia/neutrophil count decreased, thrombocytopenia/platelet count decreased, lymphopenia/lymphocyte count decreased, anemia/red blood cells decreased, febrile neutropenia, CRS, fatigue, pyrexia, decreased appetite, rash, dyspnea, sinus tachycardia/tachycardia, hypophosphatemia, headache, nausea, vomiting, increase in aspartate aminotransferase, increase in alanine aminotransferase, chills, diarrhea, hypotension, and tumor pain. Serious adverse events reported with ADP-A2M4 in two or more subjects whether considered related to the SPEAR T-cells or not include CRS, lung infection, sepsis, pyrexia, pancytopenia, atrial fibrillation, neurotoxicity, thrombocytopenia/platelet count decreased, arthralgia, and pleural effusion. Two subjects have had treatment related fatal SAE reports one subject experienced prolonged pancytopenia/aplastic anemia and the other experienced a cerebrovascular accident (stroke).
- The adverse events occurring in >10% of subjects treated with ADP-A2M10 and considered by investigators to be at least possibly related to ADP-A2M10 include leukopenia/white blood cells decreased, lymphopenia/lymphocyte count decreased, thrombocytopenia/platelet count decreased, pyrexia, CRS, peripheral edema, chills, and rash. Serious adverse events reported with ADP-A2M10 in two or more subjects whether considered related to the SPEAR T-cells or not include sepsis, CRS, rash, and acute kidney injury. One subject had a treatment related fatal SAE of prolonged pancytopenia with aplastic anemia following treatment with a second infusion of ADP-A2M10.
- As of February 3, 2020, for ADP-A2M4CD8, there have been no reports of SAEs. One subject experienced Grade 1 CRS.

As noted above, there were two SAE reports of severe prolonged pancytopenia with aplastic anemia (one patient receiving ADP-A2M4 and one patient receiving ADP-A2M10) considered by the investigator to be probably related to the SPEAR T-cells and to the lymphodepleting chemotherapy. Both of these patients died from complications of aplastic anemia related to the severe prolonged pancytopenia. In another patient, there was one report of Grade 3 neurotoxicity considered by the investigator to be probably related to the ADP-A2M4 SPEAR T-cells and, in the same patient, a later grade 5 SAE of stroke that was considered by the investigator to be possibly related to the product. These reports were communicated to the FDA and we have responded to queries from the FDA in relation to these reports. All three patients received the highest lymphodepletion regimen (fludarabine 30 mg/m2/day for 4 days and cyclophosphamide 1800 mg/m2/day for 2 days). The protocols for all of our ADP-A2M4 and ADP-A2M10 trials have now been amended to mitigate the future risk of prolonged pancytopenia and stroke, including a reduction of the lymphodepletion regimen to a previously used regimen (fludarabine 30 mg/m2/day for 4 days and cyclophosphamide 600 mg/m2/day for 3 days) to mitigate prolonged pancytopenia, and exclusion of patients with a prior history of stroke

or central nervous system bleeding (or transient ischemic attack (TIA) or reversible ischemic neurologic deficit (RIND) within the prior 6 months of treatment) to mitigate the risk of stroke. These protocol changes have been communicated to and acknowledged by the FDA. If further adverse events of a similar nature occur in patients, there is a risk that we or the FDA may impose a clinical hold until the adverse events are further evaluated or, alternatively, we or the FDA may suspend or require termination of these clinical trials.

Validation of our cell therapies requires access to human samples but there is no guarantee that such samples can be obtained 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 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 satisfaction of certain terms and conditions. There can be no guarantee that we will be able to obtain samples in sufficient quantities to enable development of and use of the full preclinical safety testing program for all cell therapies undergoing research and development. 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.

Cell therapies including our SPEAR T-cells and their potential associated risks are still under investigation. There is no guarantee that any of our cell therapies including our SPEAR T-cells will work in the way that we currently anticipate or that affinity modification of the receptors within T-cells or other cellular therapies will produce the anticipated enhancements in activity. For example, there is a potential risk that, given that the TCR chains in our SPEAR 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 SPEAR T-cells 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. There is also no guarantee that following modification of the relevant SPEAR T-cell or other cell therapy, such modified cell therapy will remain suitable for patient treatment, that it will eliminate the risk of mispairing of TCR chains or that regulatory approval will be obtained at all or on a timely basis 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 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. There is an inherent risk that the number of target peptides that can be identified and/or our ability to develop and isolate suitable receptors for affinity enhancement could be significantly lower than projected or that no additional cell therapies suitable for further development can be identified. Any failure to identify and validate further target peptides will reduce the number of potential SPEAR T-cells and other 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 SPEAR T-cells.

In addition, there is no guarantee that our attempts to develop further SPEAR T-cells will result in candidates for which the safety and efficacy profiles enable progression to and through preclinical testing. Failure to identify further candidates for progression into preclinical testing and clinical programs will significantly impact our commercial returns, increase our reliance on the success of our existing SPEAR T-cell programs and may significantly harm our business, prospects, financial condition and results of operations. 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. We have multiple research projects ongoing both internally and with third parties, for example Universal Cells, Inc., Noile-Immune Biotech, Inc., Alpine Immune Sciences Inc. and Bellicum, Inc. The outcomes of these research projects are uncertain and such research projects may or may not generate cell therapies with profiles suitable for further development or progression into clinical trials.

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

Conduct of clinical trials is dependent on 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. It is difficult to predict how quickly we or our collaborators will be able to recruit suitable patients, find suitable sites, begin clinical programs and administer our cell therapies including our SPEAR T-cells. The patient population in which any required peptide antigen is presented 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 SPEAR T-cells. Any delay in identification of suitable patients will result in the Company incurring additional costs associated with the need to find and initiate additional clinical trial sites. 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 and implemented at applicable clinical trial sites.

Our and our collaborator's clinical trials will compete with other clinical trials that are in the same therapeutic areas as our cell therapies, which will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, GSK is also opening T-cell therapy clinical trials in synovial sarcoma and MRCLS in the U.S. and European Union which could impact the number of sites available to us to run our ADP-A2M4 trials in the same indications and the number and types of patients in these indications available to us. Because the number of qualified clinical investigators is limited, we will conduct some of our clinical trials at the same clinical trial sites where competing trials are ongoing, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. 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. In addition, in relation to any indication, the standard of care for patients in that indication may change or further develop meaning that clinical sites are no longer prepared to continue with any clinical trial or require amendments to agreed protocols for clinical trials. For example, the standard of care in melanoma changed during the course of our clinical trials in melanoma with the NY-ESO SPEAR T-cell and as a result the clinical trial was halted due to anticipated unavailability of patients. 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.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result, 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 and our collaborator's ability to advance the development of our SPEAR T-cells and other cell therapies.

Comparability studies related to the manufacturing of any cell therapies may be required ahead of any pivotal trial start date or ahead of use in the European Union or alternatively in connection with any changes made to our manufacturing process, including changes in certain third party suppliers. The requirement to carry out such comparability studies or other similar studies may delay the uptake of any changed process, start of any pivotal trial or use of the relevant cell therapy. If the results from the comparability studies are not acceptable, this may further delay

the start of such trials or changed process and require re-evaluation of the process used to manufacture of such cell therapy.

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 ADP-A2M4.

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, in our ADP-A2M4 trial 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.

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 premarket 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 United States 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 do not have experience or capabilities in developing or commercializing these companion diagnostics and plan to rely in large part on third parties to perform these functions.

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 SPEAR T-cells, 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 MAGE-A4 antigen in synovial sarcoma and MRCLS may result in delays to any marketing approval for ADP-A2M4. 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.

Manufacturing and administering cell therapies is complex and we and our collaborators may encounter difficulties in production, particularly with respect to process development or scaling up manufacturing capabilities. If we or our collaborators encounter such difficulties, our or our collaborators' 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 including our SPEAR T-cells involves complex processes, including manufacture of a lentiviral delivery vector containing the gene for our affinity-enhanced engineered receptor. Administration of SPEAR T-cells includes harvesting white blood cells from the patient, isolating certain T-cells from the 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. 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 (for example the
  FDA in the United States) 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;
- 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 obtain manufacturing slots from third party contract manufacturers or to have enough manufacturing slots (including those at our Navy Yard facility) to manufacture cell therapies for patients as and when those patients require manufacture;
- Inability to procure starting materials or to manufacture starting materials (including at our UK vector facility), for example vector required for SPEAR T-cell manufacture;
- Loss of or close-down of any manufacturing facility used in the manufacture of our cell therapies. For example, we will be manufacturing cell therapies at our Navy Yard manufacturing facility. Should there be a contamination event at the facility resulting in the close-down of that facility it may not be possible to find alternative manufacturing capability for these cell therapies within the timescales required for ongoing clinical trials. 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; and
- 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.

The requirements for manufacture and supply of cell therapies for clinical trials in Europe have additional complexities and the manufacture and supply of cell therapies is raising issues which have not previously been regulated or observed by the relevant regulatory authorities. For example, supply of SPEAR T-cells for European clinical trials will either require manufacture of SPEAR T-cells in the United States or use of a new CMO in Europe. Where manufacture continues in the United States, there is a need to transfer patient product from clinical sites in Europe to the manufacturer in the United States, for the patient product to be converted into our end SPEAR T-cell product, for that

product to be released for use in Europe and then for that SPEAR T-cell 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 in the supply and manufacturing chain. Any inability to set up acceptable manufacturing and supply chains to enable treatment of patients in Europe could result in a delay to those trials starting in Europe or could result in a delay in patient treatment, requirement to re-apherese a patient or a requirement to re-manufacture patient material.

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. In addition, such changes may require amendments to be made to regulatory applications or comparability tests to be conducted which may further delay the timeframes under which modified manufacturing processes can be used for any cell therapy. 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.

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, 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. In addition, we may ultimately be unable to reduce the expenses associated with our SPEAR T-cells to levels that will allow us to achieve a profitable return on investment.

We have a platform process which may enable us to treat patient populations with an 'off-the-shelf' product. We have entered into an alliance with Universal Cells, Inc. to further develop that platform process. However, there is no guarantee that our research program or the research program with Universal Cells, Inc. will be successful, will be carried out within the timescales currently anticipated, or even if successful will result in a cell therapy that can be used to treat patients or that such cell therapy will allow us to achieve a profitable return on investment.

We have insurance to cover certain business interruption events which is capped at £10 million in the United Kingdom and \$5 million in the United States. 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 FDA regulations and foreign regulations relating to the quality and reliability of such processes. 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 US manufacturing facility and plan to manufacture vector at a UK vector facility, there is no guarantee that regulatory authorities will not raise non-compliance issues or that regulatory authorities may require us to make changes to the way in which either facility is operated. 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. In addition, there is no guarantee that any cell therapy or vector produced in any of our facilities will be able to meet regulatory requirements or that we will be able to recruit and maintain sufficient staff to enable manufacture of products within required timescales. Resourcing of cell manufacturing facilities is increasingly competitive, which restricts 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.

The outcome of clinical trials is uncertain and 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 (whether sponsored by us, a collaborator or investigator-initiated) 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 therapies are novel and unproven, and regulators will therefore require evidence that the cell therapies are safe before permitting clinical trials to commence and evidence that the cell therapies are safe and effective before granting any regulatory approval. In particular, because our cell therapies are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in each target indication. 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 the SPEAR T-cells may not be sufficient to obtain regulatory approval unless we or our collaborators can also show an adequate duration of response.

The regulatory authorities (including the FDA) may issue a hold on our or our collaborators' 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 our collaborators and will inevitably delay progression of the clinical trials concerned, if such clinical trials progress at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical programs and early clinical trials does not ensure that later clinical trials will be successful. Moreover, the results of preclinical programs and early clinical trials of cell therapies may not be predictive of the results of later-stage clinical trials. To date, we have only obtained interim results from Phase 1/2 clinical trials that are uncontrolled, involve small sample sizes and are of shorter duration than might be required for regulatory approval. There may be other reasons why our early clinical trials are not predictive of later clinical trials. In addition, the results of trials in one set of patients or line of treatment may not be predictive of those obtained in another and protocols may need to be revised based on unexpected early results.

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 cannot therefore guarantee that we will be successful in demonstrating the required efficacy and safety profile from the performance of any of our clinical programs.

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 SPEAR T-cell trials includes dose escalation and therefore efficacy data may not be obtained from initial patients treated in such studies during the dose escalation phase.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we or our collaborators do. Accordingly, more trials may be required before we can submit any cell therapy for regulatory 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 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.

We have limited experience conducting later stage clinical trials which may cause a delay in any clinical program and in the obtaining of regulatory approvals.

Although we have recruited a team that has significant experience with clinical trials, as a company we have limited experience in conducting clinical trials through to regulatory approval. In part because of this lack of experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. Large-scale trials would require significant additional financial and management resources, and reliance on third-party clinical investigators, contract research organizations, or CROs, or consultants. Relying on third-party clinical investigators, consultants or CROs may force us to encounter delays that are outside of our control.

Cell therapies may have undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or otherwise result in significant negative consequences.

Where any cell therapy has undesirable side effects, regulatory approval for such therapeutic may be delayed or suspended, or alternatively may be restricted to particular disease indications or states that are more limited than desirable. This could result in the failure of any products reaching the market or a reduction in the patient population for which any cell therapy can be used.

As of January 10, 2020, for ADP-A2AFP, ADP-A2M4, and ADP-A2M10:

- The adverse events occurring in >10% of subjects treated with ADP-A2AFP and considered by investigators to be at least possibly related to ADP-A2AFP include neutropenia/neutrophil count decreased, leukopenia/white blood cell count decreased, lymphopenia/lymphocyte count decreased, thrombocytopenia/platelet count decreased, hypoalbuminemia, febrile neutropenia, pyrexia, increase in alanine aminotransferase, increase in aspartate aminotransferase, increase in alkaline phosphatase, diarrhea, vomiting, CRS, dyspepsia, hyperkalemia, lethargy, cognitive disorder, hypotension, pain in extremity, and muscular weakness. Serious adverse events reported with ADP-A2AFP whether considered related to the SPEAR T-cells or not include CRS, bile duct obstruction and abdominal pain.
- The adverse events occurring in >10% of subjects treated with ADP-A2M4 and considered by investigators to be at least possibly related to ADP-A2M4 include neutropenia/neutrophil count decreased, thrombocytopenia/platelet count decreased, lymphopenia/lymphocyte count decreased, anemia/red blood cells decreased, febrile neutropenia, CRS, fatigue, pyrexia, decreased appetite, rash, dyspnea, sinus

tachycardia/tachycardia, hypophosphatemia, headache, nausea, vomiting, increase in aspartate aminotransferase, increase in alanine aminotransferase, chills, diarrhea, hypotension, and tumor pain. Serious adverse events reported with ADP-A2M4 in two or more subjects whether considered related to the SPEAR T-cells or not include CRS, lung infection, sepsis, pyrexia, pancytopenia, atrial fibrillation, neurotoxicity, thrombocytopenia/platelet count decreased, arthralgia, and pleural effusion. Two subjects have had treatment related fatal SAE reports - one subject experienced prolonged pancytopenia/aplastic anemia and the other experienced a cerebrovascular accident (stroke).

- The adverse events occurring in >10% of subjects treated with ADP-A2M10 and considered by investigators to be at least possibly related to ADP-A2M10 include leukopenia/white blood cells decreased, lymphopenia/lymphocyte count decreased, thrombocytopenia/platelet count decreased, pyrexia, CRS, peripheral edema, chills, and rash. Serious adverse events reported with ADP-A2M10 in two or more subjects whether considered related to the SPEAR T-cells or not include sepsis, CRS, rash, and acute kidney injury. One subject had a treatment related fatal SAE of prolonged pancytopenia with aplastic anemia following treatment with a second infusion of ADP-A2M10.
- As of February 3, 2020, for ADP-A2M4CD8, there have been no reports of SAEs. One subject experienced Grade 1 CRS.

As noted above, there were two SAE reports of severe prolonged pancytopenia with aplastic anemia (one patient receiving ADP-A2M4 and one patient receiving ADP-A2M10) considered by the investigator to be probably related to the SPEAR T-cells and to the lymphodepleting chemotherapy. Both of these patients died from complications of aplastic anemia related to the severe prolonged pancytopenia. In another patient, there was one report of Grade 3 neurotoxicity considered by the investigator to be probably related to the ADP-A2M4 SPEAR T-cells and, in the same patient, a later grade 5 SAE of stroke that was considered by the investigator to be possibly related to the product. These reports were communicated to the FDA and we have responded to queries from the FDA in relation to these reports. All three patients received the highest lymphodepletion regimen (fludarabine 30 mg/m2/day for 4 days and cyclophosphamide 1800 mg/m2/day for 2 days). The protocols for all of our ADP-A2M4 and ADP-A2M10 trials have now been amended to mitigate the future risk of prolonged pancytopenia and stroke, including a reduction of the lymphodepletion regimen to a previously used regimen (fludarabine 30 mg/m2/day for 4 days and cyclophosphamide 600 mg/m2/day for 3 days) to mitigate prolonged pancytopenia, and exclusion of patients with a prior history of stroke or central nervous system bleeding (or transient ischemic attack (TIA) or reversible ischemic neurologic deficit (RIND) within the prior 6 months of treatment) to mitigate the risk of stroke. These protocol changes have been communicated to and acknowledged by the FDA. If further adverse events of a similar nature occur in patients, there is a risk that we or the FDA may impose a clinical hold until the adverse events are further evaluated or, alternatively, we or the FDA may suspend or require termination of these clinical trials.

CRS has been reported in subjects in our SPEAR T-cell trials. A subset of these reported CRS events has been Grade 3 or 4 in severity. Subjects with more severe CRS symptoms have generally responded to treatment with the anti-IL6 or anti-IL6 receptor therapy. All of our protocols now allow for use of this therapy for the treatment of cytokine release syndrome. The anti-IL6 receptor antibody (tocilizumab) has been shown to control cytokine release syndrome without abrogating the anti-tumor response.

Any unacceptable toxicities arising in ongoing clinical programs could result in suspension or termination of those clinical programs. The more SAEs that are reported the greater the risk of suspension of termination of clinical programs, even where the SAEs are unrelated to each other or to our cell therapies. Any suspension or termination may affect other SPEAR T-cells and thereby impact our ability to recognize any product revenues. Any side effects may also result in the need to perform additional trials, which will delay regulatory approval for such cell therapies, if at all, and require additional resources and financial investment to bring the relevant cell therapy to market.

In addition, the impact of cell therapies may vary from patient to patient and this may affect the number of patients who can be successfully treated with our cell therapies. Depending on the nature of the indication, certain patients may need to be excluded from treatment, which could also impact our ability to delivery therapies to some patients.

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.

### 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 must be screened for the target peptide and HLA type, which may reduce the number of patients who can be recruited for any clinical program. For example, low target peptide expression levels in the NY-ESO SPEAR T-cell and ADP-A2M10 programs affected speed of patient recruitment in certain of the clinical trials. 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.

Although the initial results in our clinical trials to date may suggest a promising tolerability profile, these results may not be indicative of results obtained in later and larger clinical trials. Long-term follow-up of patients from earlier trials may also result in detection of additional side effects or identification of other safety issues. There is no guarantee of success in any clinical trial and there is a very high attrition rate for pharmaceutical or biological compounds entering clinical trials. Any side effects or negative safety issues identified at any stage of clinical development will require additional investigation and assessment which can result in additional costs and resource requirements that could delay or potentially terminate our clinical trials.

#### We may face difficulty in enrolling patients in our clinical trials.

We or our collaborators may find it difficult to enroll patients in our clinical trials. Identifying and qualifying patients, including testing of patients for appropriate target peptides and HLA type, to participate in clinical trials of our cell therapies are critical to our success. The patient population in which any required peptide antigen is presented may be lower than expected which will increase the timescales required to find and recruit patients into the applicable clinical trial. The timing of clinical trials depends on the speed at which we or our collaborators can recruit patients to participate in testing of our cell therapies. If patients are unwilling to participate in trials because of negative publicity from adverse events or for other reasons, including competitive clinical trials for similar patient populations, negative results seen in competitive third party clinical trials utilizing similar cell therapy products, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of potential products may be delayed or prevented. These delays could result in increased costs, delays in advancing product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether. We or our collaborators may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve sufficient diversity in a given trial in order to complete our clinical trials in a timely manner. Successful execution of patient treatment and assessment of outcomes is affected by several factors including:

- eligibility criteria for the trial in question, in particular, presenting the correct HLA type and expression levels of the target antigen;
- ability to detect required expression levels of target antigens in any patient population;

- ability to detect required target antigens in any patient population and to set detection levels at an appropriate level to facilitate patient recruitment;
- severity of the disease under investigation and the type of patient being recruited into the clinical trial;
- design of the trial protocol;
- size of the patient population;
- perceived risks and benefits of the cell therapy under trial;
- novelty of the cell therapy and acceptance by oncologists;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials and ability to obtain patient insurance coverage;
- efforts to facilitate timely enrollment in clinical trials and to provide manufactured product on a timely basis;
- patient referral practices of physicians;
- changes in the underlying standard of care applicable or treatments available for the relevant indication for which a patient is being treated;
- availability of reimbursement from insurance companies in relation to the costs of clinical trials using our cell therapies which can vary between clinical sites; and
- ability to monitor patients adequately during and after treatment, for example where patients decide not to attend follow-up appointments.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

# 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 our cell therapies to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated 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 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 Government Regulation**

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our cell therapies.

We have not previously submitted a BLA to the FDA, or similar approval submissions to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the cell therapy's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our cell therapies including our SPEAR T-cells to create additional challenges in obtaining regulatory approval, if at all. For example, the FDA has limited experience with commercial development of T-cell therapies for cancer. Accordingly, the regulatory approval pathway for our SPEAR T-cells may be uncertain, complex, expensive and lengthy, and approval may not be obtained. Requests for additional information can delay the start of any pivotal or other trial or result in clinical holds being imposed on ongoing trials and there is no guarantee that the FDA will not continue to require further or additional information ahead of approving any trial whether from our collaborators or from us.

We or our collaborators could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our cell therapies in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, 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.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our cell therapies.

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 in rare instances 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 impossible. 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.

We obtained breakthrough therapy status for the NY-ESO SPEAR T-cell for the treatment of certain patients with inoperable or metastatic synovial sarcoma who have received prior chemotherapy. Following exercise of the option over the NY-ESO SPEAR T-cell program by GSK, it is not known whether such breakthrough therapy status will continue or whether GSK will apply for and obtain any accelerated approval for the NY-ESO SPEAR T-cell. In addition, we have obtained RMAT designation (Regenerative Medicine Advanced Therapy designation) from the FDA for ADP-A2M4 for the treatment of synovial sarcoma. 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 or guarantee 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.

The process of obtaining marketing approvals, both in the United States and in countries outside of the United States, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, 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 SPEAR T-cells have a beneficial risk: benefit profile for any of their proposed indications;
- 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 United States 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; and
- 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.

It is possible that no cell therapies will ever obtain the appropriate regulatory approvals necessary to commercialize the TCR therapeutics. Any delay in obtaining, or failure to obtain, required approvals would materially adversely affect our ability to generate revenue from the particular cell therapy, which would result in significant harm to our business.

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 SPEAR T-cell, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the SPEAR T-cell in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, 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 United States, 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 or our collaborators may also submit marketing authorization applications in other countries. Regulatory authorities in jurisdictions outside of the United States have 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.

We may seek breakthrough therapy or fast track designations and may pursue accelerated approval for some or all of our current SPEAR T-cells, but we may be unable to obtain such designations or, where obtained we may be unable to maintain breakthrough therapy designation or, obtain or maintain the benefits associated with such designations.

We obtained breakthrough therapy status in the United States and PRIME status in Europe for the NY-ESO SPEAR T-cell for the treatment of certain patients with inoperable or metastatic synovial sarcoma who have received prior chemotherapy. We have obtained RMAT designation (Regenerative Medicine Advanced Therapy designation) from the FDA for ADP-A2M4 in synovial sarcoma. We may seek breakthrough therapy or fast track designations for our other SPEAR T-cells in the United States or equivalent regulations elsewhere in the world.

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 SPEAR T-cell as a breakthrough therapy provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the SPEAR T-cell 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.

Breakthrough therapy designation does not change the standards for product approval. There can be no assurance that we will receive breakthrough therapy designation for any SPEAR T-cell or any particular indication. Additionally, other treatments from competing companies may obtain the designations and impact our ability to develop and commercialize our SPEAR T-cells, which may adversely impact our business, financial condition or results of operation.

We may also seek fast track designation. If a drug or biologic candidate is intended for the treatment of a serious or life-threatening condition or disease and the drug demonstrates the potential to address unmet medical needs for the condition, the sponsor may apply for fast track designation. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Even if we do apply for and receive fast track designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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 granted accelerated approval, 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 SPEAR T-cell or indication approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our SPEAR T-cell 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 SPEAR T-cell is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post approval trial of our SPEAR T-cell with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant SPEAR T-cell.

In Europe, the EMA has implemented the so-called "PRIME" (PRIority MEdicines) status 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 status, which is decided by the EMA, is reserved to medicines 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 2016, the EMA granted PRIME status to NY-ESO SPEAR T-Cell for the treatment of certain patients with metastatic synovial sarcoma who have received prior chemotherapy. We may apply for PRIME status for other of our SPEAR T-cell products. There can be no assurance that any application will be successful in obtaining PRIME status.

Even if we receive regulatory approval of our cell therapies, 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 risk evaluation and mitigation strategy 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. In addition, if the FDA or a comparable foreign regulatory authority approves 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. 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. 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;
- 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 United States 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, 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 risk: benefit balance 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 or our collaborators may not be able to obtain or maintain orphan drug exclusivity for our cell therapies.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States or, if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for these types of diseases or conditions will be recovered from sales of the product. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are

disclosed publicly by that agency. 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. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full BLA, to market the same drug for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is clinically superior to the approved drug.

The European criteria for orphan designation are different from the U.S. criteria. On the one hand, the prevalence criterion is five in 10,000 individuals in the European Economic Area (EU plus Iceland, Liechtenstein and Norway). On another hand, no therapy is available for the rare condition or, if such a therapy exists, the future orphan product must bring a significant benefit over that therapy. The significant benefit may be any benefit to patients, including improved safety, improved efficacy, better quality of life or better patient compliance to treatment, provided that it is significant. It must be demonstrated by means of a comparison with the other available therapies, including the medicinal products already approved for the same rare condition. The Committee for Orphan Medicinal Products, or COMP, examines if the orphan criteria are met, and the orphan status is granted by a decision of the European Commission. The meeting of the criteria for orphan designation is examined again by the COMP at the time of approval of the medicinal product. If the criteria for orphan designation are no longer met at that time, the European Commission withdraws the orphan status.

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 United States and 10 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 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. A drug is clinically superior if it is safer, more effective or makes a major contribution to patient care.

There can be no assurance that any of our cell therapies will be eligible for orphan drug designation in the United States or in other jurisdictions or that it will obtain orphan drug marketing exclusivity upon approval or that we or GSK will not lose orphan drug designation for ADP-A2M4 or the NY-ESO SPEAR T-cell. Inability to obtain orphan drug designation for a specific cell therapy or loss of such designation for ADP-A2M4 or the NY-ESO SPEAR T-cell 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 extent of market exclusivity which is obtained may also be affected if the indication for any relevant registration or pivotal trial is narrower than the orphan designation granted. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

### 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 United States 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).

Because administration of cell therapies is patient-specific, the process requires careful handling of patient-specific products and fail-safe tracking, namely the need 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.

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 also use radioactive reagents and materials in our research and development in the United Kingdom. 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 capped at £10.0 million per occurrence and public liability insurance capped at £3.0 million per occurrence; 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 United Kingdom and the United States, and authorities in the European Union, 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 United Kingdom, United States 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 United States, 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, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or kind, in exchange for, or to induce, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers on the other. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Healthcare Reform Act, amended the intent requirement of the Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Under federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the Anti-Kickback Statute and analogous state law requirements;
- the False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly
  presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors
  that are false or fraudulent. Violations under the Anti-Kickback Statute and certain marketing practices,
  including off-label promotion, also may implicate the FCA. In addition, private individuals have the ability to
  bring actions on behalf of the government under the FCA and under the false claims laws of several states;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information

related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. The CMS publishes the reported data in a searchable form on an annual basis;

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability
  for executing a scheme to defraud any healthcare benefit program or making false statements relating to
  healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which
  governs the conduct of certain electronic healthcare transactions and protects the security and privacy of
  protected health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to: items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance issued by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. California and a few other states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals. In addition, several states impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that, once we begin marketing our product(s) some of our practices may be challenged under these laws. While we intend to structure our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. 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.

Our current cash projections include reliance on the ability to obtain certain tax credits and the operation of certain tax regimes within the United Kingdom. Should these cease to be available, 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. 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%. 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.

We may not be able to continue to claim research and development tax credits (R&D tax credits) in the future as we increase our personnel and expand our business because we may no longer qualify as an SME (small or medium-sized enterprise). In order to qualify as an SME for R&D tax credits, we must continue to be a company with fewer than 500 employees and also have either an annual turnover not exceeding  $\le 100$  million or a balance sheet not exceeding  $\le 86$  million.

We may also benefit in the future 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 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 United Kingdom 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.

#### Risks Related to the Commercialization of Our SPEAR T-cells

### 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 opportunity to receive third-line therapies, which tend to be more novel therapies. Our and our collaborators current clinical trials generally require that patients have received chemotherapy prior to enrollment. Depending upon the outcome of current trials, we or our collaborators may conduct future clinical trials using cell therapies for first-line therapy, but there can be no guarantee that clinical trials will be approved or that if approved such trials will 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.

Our estimates of the patient population that may be treated by our cell therapies is based on 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. Current SPEAR T-cells have been developed for patients who are HLA A2 which will reduce the size of the patient population that can be treated unless we develop and we or our collaborators receive regulatory approval for cell therapies approved for additional HLA peptides.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our cell therapies, we may not be able to generate product revenue.

As an organization, we have never marketed or supplied commercial pharmaceutical or biologic products or therapies. We do not currently have a sales force and will need to grow and develop the sales function and associated support network if we are to supply cell therapies on a commercial basis. As our cell therapies proceed through clinical programs, we intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain 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 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. We also face significant competition in our search for third parties to assist us with the sales and marketing efforts of our cell therapies. Such competition may also result in delay or inability to supply cell therapies to particular countries or territories in the world which in turn will restrict the revenue that can be obtained from any cell therapy. 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 United States 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. For example, we may be sued if any of our SPEAR T-cells 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;
- 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 currently hold £15.0 million in clinical trial insurance coverage in the aggregate per year, with a per trial limit of £5.0 million. We also hold products and services liability insurance capped at £3.0 million in the aggregate and public liability insurance capped at £3.0 million per occurrence. These levels may not be adequate to cover all liabilities that we may incur. We may also need to increase our insurance coverage as we expand the scope of our clinical trials and commercialize any of our cell therapies. In addition, insurance coverage is increasingly expensive. 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 SPEAR T-cells 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 SPEAR T-cells 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;
- 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 including SPEAR T-cells. 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 or our collaborators will not be able to generate significant revenue.

Even if our cell therapies achieve market acceptance, we or our collaborators 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 and reimbursement may be limited or unavailable in certain market segments for cell therapies, which could make it difficult for us or our collaborators to sell cell therapies profitably.

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.

In the United States, 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.

We intend to seek approval to market our cell therapies in both the United States and in selected jurisdictions. If we obtain approval in one or more foreign jurisdictions for our cell therapies, we will be subject to rules and regulations in those jurisdictions.

In some foreign countries, particularly those in the European Union, 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.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the recently enacted U.S. Healthcare Reform Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our SPEAR T-cells and other cell therapies, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs.

This includes aggregate reductions of Medicare payments to providers up to two percent per fiscal year, which went into effect on April 1, 2013 and will remain in effect until 2024, unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of 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 result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

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

We rely on GSK in relation to the performance of programs under the GSK Collaboration and License Agreement and associated payments.

Performance of the GSK Collaboration and License Agreement and the extent to which further targets are nominated under that agreement depend on decisions taken by GSK. We have no control over whether GSK will elect to progress additional targets under the collaboration arrangements and therefore trigger additional payments from GSK under the GSK Collaboration and License Agreement. GSK also has the ability to influence or control decisions taken in relation to the development of any cell therapies covered by the agreement.

The GSK Collaboration and License Agreement is effective until all payment obligations expire, including any ongoing royalty payments due in relation to GSK's sale of any covered TCR therapeutic candidates. The agreement can also be terminated on a collaboration program-by-collaboration program basis by GSK for lack of feasibility or inability to meet certain agreed requirements. Both parties have rights to terminate the agreement for material breach upon 60 days' written notice or immediately upon insolvency of the other party. GSK has additional rights to terminate either the agreement or any specific license or collaboration program upon 60 days' written notice to us. Additional payments may be due to us as a result of such termination, and where we continue any development of any TCR therapeutic candidate resulting from a terminated collaboration program, depending on the stage of development, royalties may be payable to GSK at a mid-single-digit percentage rate of net sales. We also have rights to terminate any license where GSK ceases development or withdraws any licensed SPEAR T-cells in specified circumstances.

The current development plans or any future development plan agreed upon between GSK and us, including those relating to the third target program, may be unsuccessful or fail to result in candidate therapies that are feasible for further development or commercialization. Changes to the development plans or collaboration agreement may impact the timing and extent of milestone payments made by GSK to us, the nature of the relationship with GSK or the scope of the collaboration with GSK.

There is no guarantee that any payments due on commercialization of products under the GSK Collaboration and License Agreement will be due or payable by GSK at any time or on the timeframes currently expected. In particular, GSK has now exercised its option to the NY-ESO SPEAR T-cell program and commercialization of the NY-ESO SPEAR T-cell is now the responsibility of GSK. The timing for commercialization of the NY-ESO SPEAR T-cell and the route to commercialization will be determined by GSK and we cannot guarantee that GSK will commercialize the NY-ESO SPEAR T-cell within expected timelines or at all.

Under the GSK Collaboration and License Agreement, we are also prohibited from independently developing or commercializing therapies directed at the targets subject to outstanding options granted to GSK. All intellectual property rights arising from the performance of the collaboration and license agreement will be jointly owned apart from intellectual property rights that we solely create. Both GSK and we have freedom to use jointly owned intellectual property rights.

The relationship with GSK could also result in disputes arising between us and GSK which could result in costly arbitration or litigation and could impact the ongoing clinical programs or progress of such clinical programs.

We rely on Universal Cells Inc in relation to the performance of collaboration agreements between us and Universal Cells Inc for the further development of 'off-the-shelf' cell therapies.

Development of allogeneic T-cell therapies and our ability to commercialize those allogeneic T-cell therapies may depend heavily on the performance of Universal Cells under the ongoing collaboration (the "Universal Cells Collaboration") and payments made by Universal Cells to us in relation to such development.

Under the Universal Cells Collaboration, the parties will agree on up to three targets and will co-develop T-cell therapies directed to those targets pursuant to an agreed research plan. For each target, Universal Cells will fund co-development up until completion of a Phase 1 trial for products directed to such target. Upon completion of the Phase 1

trial for a product, we and Universal Cells will elect whether to progress with co-development and co-commercialization of such product, or to allow the other party to pursue the candidate independently. If we progress with co-development and co-commercialization of a product, then each party will grant the other party a co-exclusive license to co-develop and co-commercialize such product in the field of T-cell therapy. If a product is developed solely by one party, then the other party will grant to the continuing party an exclusive license to develop and commercialize such product in the field of T-cell therapy. Universal Cells will also have the right to select two targets and develop allogeneic T-cell therapy candidates independently. Universal Cells will have sole rights to develop and commercialize these products, subject to necessary licenses and the payment of milestones and royalties. The targets to be developed and the resulting therapies to be developed are currently unknown and, to the extent being co-developed, will need to be agreed between us and Universal Cells.

Under the terms of the agreement, we have received an upfront payment of \$50 million and may receive up to an additional \$847.5 million in upfront, development and sales milestones together with up to \$7.5 million in research funding per year and tiered royalties on net sales in the mid-single to mid-teen digits where Universal Cells takes cell therapy candidates forward unilaterally through development and commercialization. Where we take products forward unilaterally through development and commercialization, we may have to pay Universal Cells up to \$552.5 million in development and sales milestones. In addition, Universal Cells would receive tiered royalties on net sales in the mid-single to mid-teen digits. To the extent that we and Universal Cells co-develop and co-commercialize any therapies, we will equally share the costs of such co-development and co-commercialization, with the resulting profits from co-commercialization also shared equally. There is no guarantee that any research funding, development or sales milestones or product royalties or any other sums will become due or payable to us at any time or on the time frames currently expected.

Universal Cells has a right to terminate programs under the Universal Cells Collaboration and the agreement in whole or in part for convenience, on provision of prior written notice. 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. Termination may also impact our ability to access and use certain Universal Cells technology within our own allogeneic platform and products arising from that platform.

Any research or development plan agreed upon between Universal Cells and us may be unsuccessful or fail to result in therapies that are feasible for further development or commercialization. In addition, milestone payments and research funding may not be paid or may be varied where any research or development plan is amended or where any research or development plan is terminated prior to completion. There is no guarantee that any payments due or payable on commercialization of products under the Universal Cells Collaboration will be due or payable at any time or on the timeframes currently expected. The timing for commercialization of any products under the Universal Cells Collaboration is currently unknown and will depend on the targets selected and the type of allogeneic T-cell therapy being developed.

Any research and development plans for allogeneic T-cell therapies under the Universal Cells Collaboration will be subject to change as a result of risks inherent with the development of any pharmaceutical, biological or gene therapy product. Changes may be agreed to expand or change the scope of the collaboration or the responsibilities of the parties under the collaboration. 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 Universal Cells or the scope of the collaboration. Delay in performance of responsibilities under any research or development plan could impact our ability to progress T-cell therapies through research and development, including where Universal Cells delays the performance of any of its responsibilities. In addition, risks identified during the Universal Cells Collaboration may impact the development of our own allogeneic therapies outside of the collaboration with Universal Cells.

Universal Cells has the ability to influence or control certain decisions relating to the development of therapies covered by the Universal Cells 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. Under the Universal Cells Collaboration, restrictions apply to the ability of either

party to independently develop or commercialize certain competing T-cell therapies directed to the same targets as those nominated under the collaboration. In addition, Universal Cells or its affiliates may have competing internal or commercial interests which could impact our collaboration or Universal Cells' decision to take any clinical programs forward to the next stage. This could increase the costs required to further develop or commercialize any therapy or impact on our ability to take any therapy into further development and commercialization.

The relationship with Universal Cells could also result in disputes arising between us and Universal Cells, which could result in costly arbitration or litigation and could adversely impact the progress of research and development programs or progress of such clinical programs.

Commercialization of any cell therapies arising from the Universal Cells Collaboration additionally requires a license from iPS Academia Japan, Inc under certain intellectual property rights owned by IPS Academia Japan, Inc. Although licenses are available, there is no assurance that the license can be obtained on commercially acceptable terms.

## We rely heavily on ThermoFisher and the technology that we license from them.

The ability to use the ThermoFisher Dynabeads® CD3/CD28 technology to isolate, activate and expand T-cells is important to our ongoing ability to offer SPEAR T-cells. In December 2012, we entered into a series of license and sublicense agreements with Life Technologies Corporation (now part of ThermoFisher), such agreements having been amended as of November 2019. These agreements provide us with a field-based non-exclusive license under certain intellectual property rights owned or controlled by ThermoFisher in relation to the methods of use of the ThermoFisher Dynabeads® CD3/CD28 technology to isolate, activate and expand T-cells and enable transfection of the T-cells with any TCR genes to manufacture our TCR products and use and sell those TCR products to treat cancer, infectious disease and/or autoimmune disease. We also have a field-based non-exclusive sub-license under certain other patents which cover the method of use of the Dynabeads® CD3/CD28 and are controlled by ThermoFisher under a head-license from the University of Michigan, the United States Navy and the Dana-Farber Cancer Institute.

In June 2016, we entered into a supply agreement with ThermoFisher for the supply of the Dynabeads® CD3/CD28 technology. The supply agreement runs until December 31, 2025.

ThermoFisher has the right to terminate the above described agreements for material breach or insolvency. On termination of the license agreements, the supply agreement will also automatically terminate. If ThermoFisher terminates the exclusive license, sub-license and supply agreements or otherwise refuses or is unable to supply the Dynabeads® product, we will have to seek an alternative source of the beads or develop an alternative process methodology to enable supply of our cell therapies.

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 currently rely partly on outside contract manufacturing organizations ("CMOs") and other third parties to provide services related to the manufacture, supply, and processing of our cell therapies. If one or more of these third parties become unable or unwilling to continue to manufacture our cell therapies (including any raw or intermediate material required for the manufacture of our cell therapies) or provide their services in the future, we may be forced to find an alternative third-party service provider, which we may not be able to do on commercially reasonable terms, if at all. Failure to identify a suitable alternative service provider could impact our business, financial condition or results of operations.

We rely on a limited number of third-party manufacturers and third party service providers for clinical trial product supplies and services at each stage of the manufacturing process, 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, if any.
- 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.
- 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.

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 United States 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 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 at a single manufacturing site, namely our Navy Yard facility. Should the Navy Yard facility be unable to manufacture our 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.

Our contract manufacturers are also subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any, of our cell therapies by the FDA or the commercialization of our cell therapies or result in higher costs or deprive us of potential product revenue. We have insurance to cover certain costs and expenses related to business interruption, which is capped at £3.0 million in the aggregate.

In addition, we will rely on third parties to perform release tests on our cell therapies prior to delivery to patients. If these tests are not appropriately performed and test data is not reliable, patients could be put at risk of serious harm. For example, if the HLA testing is not accurate then a patient without the correct HLA-type could be provided with incompatible cell therapies and as a result such patient could suffer severe side effects or fatality.

We also rely on certain third parties to assist us in the future development of cell therapies including next generation SPEAR T-cells and manufacture and supply of SPEAR T-cells for patient administration. For example, we have research collaborations with Noile-Immune and Alpine Immune Sciences in which we are looking to develop next generation cell therapy approaches. As with any research and development program there is no guarantee of the success of such program or that such program will be carried out by us or our collaborators within the timescales we currently anticipate.

We have a shared development history with Immunocore, and as a result jointly own certain intellectual property rights which are required for our ongoing business.

Our TCR technology was originally developed by Avidex, which was subsequently acquired by Medigene in 2006. We were formed as a new, separate company and licensed our TCR technology for T-cell therapy from Medigene

in July 2008. Immunocore was subsequently formed as a new separate company and acquired the TCR technology for soluble TCRs from Medigene later in 2008 to develop soluble TCR proteins. Certain of our shareholders also hold shares in Immunocore.

Since January 1, 2018, the Company no longer considers Immunocore to be a related party due to several factors including the mutual termination of the target collaboration agreement that terminated effective March 1, 2017, our lack of common directors and the decrease in Immunocore's share ownership in 2017 to less than 5% of our ordinary shares. However, under the terms of that target collaboration agreement, we will continue to share a database of identified targets with Immunocore which resulted from the joint target identification efforts under that agreement.

In addition, many of the patents relating to our underlying core technology in TCR engineering, are co-owned by us and Immunocore pursuant to a separate assignment and license agreement. Under this agreement, both Immunocore and Adaptimmune utilize the jointly owned patents and know-how, with Adaptimmune focused on the treatment of patients with engineered SPEAR T-cells and Immunocore focused on the treatment of patients with soluble TCRs. Under the agreement, each of Immunocore and Adaptimmune grants the other an exclusive, royalty-free, irrevocable license, with the right to sublicense, to certain jointly owned patents and know-how. However, there is the potential that Immunocore could develop a soluble TCR product targeting the same cancer target that one of our cell therapies is targeting, and therefore compete directly with us.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our cell therapies.

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. We cannot provide assurances that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of subjects. Our failure or any failure by these third parties to comply with these regulations or to support BLA for approval of any of our cell therapies for the treatment of a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. 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.

#### We rely on third parties to obtain reagents and raw materials.

The manufacture of our cell therapies requires access to a number of reagents and other raw materials from third parties. Such third parties may refuse to supply such reagents or other raw materials or alternatively refuse to supply on commercially reasonable terms. There may also be capacity issues at such third-party suppliers that impact our ability to increase production of our cell therapies.

Some of the materials used in the manufacture and processing of our cell therapies may only be supplied by one or a few vendors, which means that, should those vendors be unable to supply, for whatever reason, our ability to manufacture cell therapies and progress cell therapies through clinical trials could be severely impacted and result in additional delays. Such failure to supply could also impact other supply relationships with other third parties and potentially result in additional payments being made or required in relation to such delays. In addition, where any raw material or precursor material (including, for example, lentiviral delivery vector, medium or other essential raw material) is currently supplied by one or a few vendors, replacing such raw material or precursor or finding alternative vendors may not be possible or may significantly impact on the timescales for manufacture and supply of our cell therapies. Even where alternative materials or precursors or alternative vendors are identified, such alternative materials, precursors or vendors will need to be properly assessed, validated and qualified and additional regulatory approvals may also need to be obtained all of which could result in significant delays to the supply of our cell therapies or an inability to supply our cell therapies within anticipated timescales, if at all.

## We rely on third parties for equipment and components necessary to manufacture our cell therapies.

As we further develop our manufacturing process, the manufacture of our cell therapies may require access to specialized or customized equipment and components from third parties. Such third parties may refuse to supply such equipment and components or alternatively refuse to supply on commercially reasonable terms. There may also be capacity issues at such third-party suppliers that impact our ability to manufacture our cell therapies.

Some of the equipment and components used in the manufacture and processing of our cell therapies may only be supplied by one or a few vendors, which means that, should those vendors be unable to supply, for whatever reason, our ability to manufacture cell therapies and progress cell therapies through clinical trials could be severely impacted and result in additional delays. While other equipment and components may be available to perform the same or similar operational steps, such alternative equipment and components may be less efficient, more costly, and may result in production delays that may detrimentally impact timescales for the manufacture and supply of our cell therapies. Even where alternative equipment and components are available, such alternatives will need to be properly assessed, validated and qualified and additional regulatory approvals may also need to be obtained all of which could result in significant delays to the supply of our cell therapies or an inability to supply cell therapies within anticipated timescales, if at all.

We have formed and may form or seek collaboration agreements or enter into additional licensing arrangements with third parties and either fail to realize the benefits of such relationships or incur substantial additional costs in performing such relationships.

We have formed and may form or seek further third party alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development, manufacturing and commercialization efforts with respect to our SPEAR T-cell therapies and any future products. For any of these third party alliances we are reliant on performance of a third party to achieve the end aims of the alliances. For example, we have a collaboration agreement with Universal Cells Inc. ("Universal") under which Universal is required to perform certain collaboration activities. Any delays in the performance of these activities or any requirement to amend or modify those activities will result in delay to the overall program. Any of these relationships may require us to incur nonrecurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. There is no guarantee that such third party relationships will result in any positive improvements to our SPEAR T-cells, cell therapies or associated manufacturing processes or that performance of such third party relationships will occur in accordance with expected timelines. Such third party alliances may result in us incurring additional costs or requiring additional resources over and above the costs and resources committed to those alliances. In addition, we face significant competition in seeking appropriate partners and the negotiation process is timeconsuming and complex. Moreover, we may not be successful in our efforts to establish third party arrangements for our cell therapies which may impact our ability to further develop our cell therapies or delay the further development of our cell therapies.

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

#### Our cell therapies could be at risk of biosimilar development.

Expedited routes or abbreviated procedures for obtaining regulatory approval for products aiming to target the same cancer peptide as any SPEAR T-cells or any of our cell therapies may be available to third parties, which we cannot control or prevent. For example, third parties could develop affinity-enhanced TCRs binding to the same targets and regulatory authorities may accept that they are interchangeable with our corresponding SPEAR T-cells and, as a result, grant regulatory approval for such competing products. Entry into the market of such competing products may impact the price of SPEAR T-cells and the extent of commercialization possible in relation to such SPEAR T-cells.

# 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 SPEAR 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 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. The scope and validity of patents in the pharmaceutical field involve complex legal and scientific questions and can be uncertain. Where appropriate, we seek patent protection for certain aspects of our cell therapies and technology. Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to patent technology in jurisdictions with significant commercial opportunities. 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. We may not develop additional proprietary products that are patentable.

Many companies have encountered significant problems in protecting and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. 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.

In addition, patents have a limited lifespan. In most countries, including the United States, 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 we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, 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.

Any loss of, or failure to obtain, patent protection could have a material adverse impact on 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. This is particularly the case where third parties are using T-cell therapies falling within the scope of our patents in clinical trials. It may not be possible to enforce our patents against such third parties during the course of those clinical trials.

Further given that our technology relates to the field of genetic engineering, political pressure or ethical decisions may result in a change to the scope of patent claims for which we may be eligible. Different patent offices throughout the world may adopt different procedures and guidelines in relation to what is and is not patentable and as a result different protection could be obtained in different areas of the world which may impact our ability to maximize commercialization of our technology.

We may also incur increased expenses and cost in relation to the filing and prosecution of patent applications where third parties choose to challenge the scope or oppose the grant of any patent application or, following grant, seek to limit or invalidate any patent. Any increased prosecution or defense required in relation to such patents and patent applications, whether relating to this third party observation or any other third party challenge or opposition, entails

increased cost and resource commitment to the business and may result in patents and patent applications being abandoned, invalidated or narrowed in scope.

## 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. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect our intellectual property, could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our SPEAR T-cells or other cell therapies or have additional, material adverse effects upon our business, results of operations and financial condition.

In addition, we provide samples to third parties under material transfer agreements, including to research institutions or other organizations that we cannot control. There is a risk that such third parties could disclose details of those samples or carry out further research in relation to provided samples which results in intellectual property rights that block our future freedom to operate, and to which we may not be able to obtain a license on commercially acceptable terms or at all. In addition, provision of samples and our confidential information to such parties could facilitate or assist such parties in development of competing products.

# 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 United States, involving patents and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we or our third party suppliers are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third-party proprietary technologies we have licensed. 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. Our competitive position could suffer as a result. In addition, if we have declined to enter into a valid non-disclosure or assignment agreement for any reason, we may not own an invention or intellectual property rights and may not be adequately protected. Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our cell therapies, we have not conducted a full freedom-to-operate search or analysis for such cell therapies, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our cell therapies. Thus, we cannot guarantee that we can successfully commercialize our cell therapies in a way that will not infringe any third party's intellectual property.

#### 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 SPEAR T-cells. 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. For example, commercialization of iPSC derived 'off-the-

shelf' cell therapies are likely to require a license from iPS Academia Japan Inc under intellectual property rights covering the generation of iPSC cell lines.

We may also require licenses under third-party patents covering certain peptide sequences or the use of those peptides. Such licenses will require payment of sums by us and we cannot guarantee that the terms of such licenses will be available on commercially acceptable terms or at all, which could limit the peptides which can be used by us and the efficacy of the final affinity- enhanced TCRs that we are able to offer.

As we change, develop and modify our manufacturing processes we may identify further third-party patents covering those developments and modifications. We cannot guarantee that we will be able to obtain licenses under these third-party patents or other intellectual property rights and as a result we may not be able to undertake the developments of modifications that we wish, either at all or in the timescales we require. This could ultimately impact our ability to deliver commercial T-cell products at the cost required.

The fees associated with such third-party licenses, including any associated up-front fees, milestone payments, and/or on-going royalty payments may be significant and may not be aligned with the value obtained by us from such licenses. For example, we may not be successful in commercializing any next-generation SPEAR T-cell products which incorporate licensed technology to offset any up-front or milestone payments we may have incurred in the development of such next-generation SPEAR T-cell products.

Further or other third-party patents and patent applications may be identified from time to time that require prospective action by us to prevent the grant of broad claims. Such prospective action requires time and expense and also impacts on the resources generally available to us.

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 SPEAR 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 SPEAR T-cells or 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 United States, 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our cell therapies. Such a loss of patent protection could have a material adverse impact our business, financial condition and results of operations.

# Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

# Our ability to protect our intellectual property rights in territories outside of the United States may vary and thus affect our ability to obtain revenue from our cell therapies.

Filing, prosecuting and defending patents on our cell therapies in all countries throughout the world would be prohibitively expensive, and the extent of intellectual property rights may be less extensive than those which can be obtained in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

# Risks Related to Employee Matters and Managing Growth

# 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; Dr. Helen Tayton-Martin, our Chief Business Officer; William Bertrand, our Chief Operating Officer; John Lunger, our Chief Patient Supply Officer and Dr. Elliot Norry, our Senior Vice President and Chief Medical Officer. Michael Garone is serving as our Interim Chief Financial Officer through March 31, 2020. Gavin Wood has been appointed to serve as our Chief Financial Officer effective from April 1, 2020. 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. To induce employees to remain at our company, in addition to salary and cash incentives, we have provided share options that vest over time, with higher awards of share options being made to senior employees. The value to employees of share options that vest over time may be significantly affected by movements in our share price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with all of our employees in the United Kingdom, these employment agreements provide for a mutual nine months' notice period in the case of Dr. Tayton-Martin and Mr. Wood; 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 United States, the employment agreements provide for at-will employment except that, under their employment agreements, Mr. Rawcliffe, Mr. Bertrand and Mr. Lunger must provide 60 days' written notice and our senior vice-presidents, including Dr. Norry, must provide 30 days' written notice. This means that any of our employees in the United States, except for Mr. Rawcliffe, Mr. Bertrand, Mr. Lunger and our senior vice-presidents, could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, midlevel and senior scientific and medical personnel. The uncertainty around the impact of the U.K.s exit from the European Union ("Brexit") may make it more difficult to retain and to continue to attract employees into our U.K. facilities.

# We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2019, we had 400 employees. As our development and commercialization plans and strategies develop, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our SPEAR T-cells, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our SPEAR T-cells will depend, in part, on our ability to retain employees and effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing growth activities and the resourcing of replacement employees in the event employees leave. For example, competition for employees able to perform manufacturing activities in the cell therapy area is increasing as more companies develop their own manufacturing capabilities. Should we be unable to retain key manufacturing employees, this could impact on our ability to manufacture cell therapies for our clinical trials or result in delays to patient treatment.

We also rely on third parties to provide certain of our manufacturing and quality capabilities. See "Risks Related to Our Reliance Upon Third Parties."

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our cell therapies and, accordingly, may not achieve our research, development, and commercialization goals.

## We have our own manufacturing facility which may result in increased costs being incurred by the company

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

Our ability to successfully manufacture our own cell therapies at the Navy Yard facility 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 both the United States and European Union;
- our ability to develop internal quality controls and processes sufficient to enable manufacture and supply of cell therapies at our Navy Yard facility;
- 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 facility.

Any delay or failure in manufacture at our facility could result in delays to the supply of cell therapies for our clinical programs. Should any of our third party manufacturers also cease to be able 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.

We are in the process of increasing the number of manufacturing slots available at our Navy Yard facility. The cost of developing, out-fitting and operating a larger manufacturing facility may also be greater than currently anticipated and we may require additional capital for the completion of the upscaling of the manufacturing facility which may result in the need for us to raise additional funds earlier than expected.

We cannot guarantee that we will be successful in manufacturing cell therapies at all or in a manner that complies with regulatory requirements. For example, there is a risk that any cell therapies we manufacture are contaminated or are otherwise incorrectly manufactured resulting in injury or death to any patient receiving those cell therapies. Such failure could result in a halt being placed on manufacture at our Navy Yard facility. We may also face difficulties in properly tracking and administering our cell therapies to patients, again potentially resulting in injury or death to any patient receiving those cell therapies.

We may also be unable to support use of our own manufacturing facility together with third party suppliers and become the sole supply for our cell therapies. Any inability to supply SPEAR T-cells at the required levels and to the required specifications, will result in delays to clinical trials and may result in holds being applied to such clinical trials.

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

Immunotherapy is an active area of research and a number of immune-related products have been identified in recent years that are alleged to modulate the immune system. Many of these products utilize dendritic cells, a form of immune cell that presents cancer target peptides to T cells and that can in turn result in T-cell activation. More recently, bispecific antibodies and checkpoint inhibitors (for instance PD-1/PD-L1 antibodies) have been identified as having utility in the treatment of cancer. Bi-specific antibodies commonly target both the cancer peptide and the TCR, thus bringing both cancer cells and T cells into close proximity to maximize the chance of TCR binding and hence an immune response to the cancer cells. Checkpoint inhibitors on the other hand work by targeting receptors that inhibit T-cell effectiveness and proliferation and essentially activate T cells. Other immunotherapies that are being actively investigated include: antibodydrug complexes, TCR-mimic antibodies, oncolytic viruses, cancer vaccines. A variety of cell-based autologous and allogeneic ("off-the-shelf") approaches are also being researched and developed, including but not limited to: CAR-T cell, TCR T-cell, GammaDelta T-cell, CAR-NK cell, NKT cell and CTL.

- CAR-T in hematological malignancies: Engineered T-cell therapeutics have been identified using antibody recognition systems engineered into T cells, so-called CAR-T cells. A number of targets in hematological malignancies have been well characterized including, but not limited to: BCMA, CD4, CD5, CD19, CD22, CD20, CD33, CD38, CD70, CS1 and CD123. Two CD-19 directed CAR-T cell products have been approved by the U.S. Food and Drug Administration ("FDA") Kymriah™ (tisagenlecleucel) and Yescarta™ (axicabtagene ciloleucel) as well as by the European Medicines Agency (EMA) in the European Union. More recently, Kymriah™ has been approved by the MHLW in Japan. A number of companies and academic institutions are developing CAR-T cell products including but not limited to Allogene Therapeutics, Arcellx, Atara Bio, Autolus, Baylor College of Medicine, bluebird bio, CASI Pharmaceuticals, Celyad, Celgene (now part of Bristol-Myers Squibb), Cellectis, CRISPR Therapeutics, Fate Therapeutics, Janssen (JNJ with Nanjing Legend), Juno Therapeutics (a Bristol-Myers Squibb company), Kite Pharma (Gilead), Linea Rx, Mustang Bio, Novartis, Precigen, Refuge Biotechnologies Inc, Servier, Sorrento Therapeutics, Xenetic Biosciences, Xyphos (a wholly owned subsidiary of Astellas) and Ziopharm Oncology.
- CAR-T in solid tumors: In addition to hematological malignancies, there are a growing number of pharmaceutical, biotechnology, and academic institutions researching and developing autologous and allogeneic CAR-T therapies in the solid tumor setting. These CAR-T cell therapies are at a variety of stages of preclinical and clinical development, as well as directed towards a broad target spectrum, including but not limited to: DLL3, EGFR, GD2, HER-2, IL13rα2, Lewis Y, L1-CAM, Mesothelin, MUC16, PSCA, PSMA and ROR1. Competitors include but are not limited to: Allogene Therapeutics, Amgen, Atara Bio, Aurora Biopharma, Baylor College of Medicine, Cell Medica, Bellicum, BioNTech, Carisma Therapeutics (formerly CARMA Therapeutics), Carsgen, Celgene (now part of Bristol-Myers Squibb; with Obsidian Therapeutics) Cellectis Therapeutics, Celyad, CRISPR Therapeutics, Endocyte (a Novartis Company), Fate Therapeutics, Formula Therapeutics, Fred Hutchinson Cancer Research Center, Helix BioPharma, Juno Therapeutics (a Bristol-Myers Squibb company), Lyell Immunopharma (with GSK), MaxCyte, Memorial Sloan Kettering Cancer Center, Minerva Biotechnologies, Mustang bio, OncoSec Immunotherapies, Oncternal Therapeutics, Poseida Therapeutics, Precigen, Senti Biosciences, Sorrento Therapeutics, Symvivo, Targazyme, Tmunity, Xyphos (a wholly owned subsidiary of Astellas).
- CARs & TCR-mimics targeting peptide-HLA complexes: Most CAR-T therapies in development are directed towards suitable antigen targets. Another area of development is the creation of CAR-T that selectively binds to the peptide-HLA (pHLA) complex (the natural binding site for endogenous TCR). Furthermore, competitors are also looking at pHLA antibodies or TCR mimic antibodies that can either be engineered in T-cells or developed as standalone antibody therapies in cancer indications (both hematologic malignancies and solid tumors). Targets of such pHLA CAR-T or TCR mimic antibodies include: AFP, CD19, BCMA, NY-ESO-1, p53 and WT1. A number of pharmaceutical, biotechnology, and academic institutions are researching and developing CARs & TCRmimics targeting the peptide-HLA complex, including but not limited to: Adicet Bio / Regeneron, Altor Bioscience, Cancer Research Technology/CRUK, Eureka Therapeutics, Gritstone Oncology, MorphoSys, Xencor and Ziopharm Oncology.
- TCR T-cells: TCR T-cells are being developed by competitors that are directed towards a multitude of targets including: AFP, CD20, HPV-16 E6/E7, KRAS, MAGE-A1, MAGE-A3, MAGE A3/A6, MART1, NRAS, NY-

ESO-1, p53, PRAME, TGFBRII frameshift antigen WT1, as well as personalized neoantigens. Juno Therapeutics (a Bristol-Myers Squibb company) has developed an engineered TCR therapeutic candidate where the end TCR is purported to have enhanced affinity through stem-cell selection, Juno's candidate JTCR016 (WT1-specific TCR), in collaboration with Fred Hutchinson Cancer Research Center and the National Cancer Institute (NCI), is currently undergoing a Phase 1/2 trial in NSCLC and mesothelioma setting as well as a separate Phase 1/2 in AML. Medigene AG has reported development of a PRAME TCR therapeutic candidate (MDG1011), which has begun a Phase 1/2 clinical investigation in AML, MM and myelodysplastic syndromes. In addition to Juno there is a growing number of TCR companies that are adopting approaches to TCR affinity enhancement, for example Axis Therapeutics, Takara, Takara Bio, Fred Hutchinson Cancer Centre and Immatics. In addition other TCR-focused competitors include, but are not limited to: 3T, Adaptive Biotechnologies (with Genentech), AgenTus, Atreca, Baylor College, Bellicum, BioNTech (with Eli Lilly), bluebird bio, BlueSphere bio, Captain T cell, Celgene (now part of Bristol-Myers Squibb; with Immatics), Cellular Biomedicine Group Inc, Cell Medica Ltd, Cytovant Sciences, Ervaxx, GigaMune, GSK, HighPass Bio (an Elevate bio company), Immunocellular Therapeutics, Immunocore, Intellia Therapeutics, Inc. (with Ospedale San Raffaele), Juno Therapeutics (a Bristol-Myers Squibb company), Kiromic, Kite Pharma (Gilead), Lion TCR LTD, MD Anderson Cancer Center, MediGene AG, NCI, Neon Therapeutics, PACT Pharma, Parker Institute, Refuge Biotechnologies Inc., Roswell Park Cancer Institute, Scancell (with BioNTech), Tactiva Therapeutics, Takara Bio Inc, Takeda (T-CIRA), TCR Cure, T-Cure, TCR x immunotherapies, T-Knife, Tmunity, TScan Therapeutics, University of Leiden, Zelluna (with Oslo University Hospital) and Ziopharm Oncology.

There are a number of different approaches being developed for allogeneic or "off-the-shelf" immunotherapy products including stem-cell derived products, HLA-matched products, healthy-donor derived products and use of cells with no or limited HLA type (for example GammaDelta T-cell, or NK cells). Competitors include Allogene Therapeutics (with Notch Therapeutics), Century Therapeutics (with FujiFilm Cellular Dynamics), City of Hope (with Mustang Bio), Editas, Fate Therapeutics, Takeda (in collaboration with CiRA), Thyas, Editas, UCLA and T-CiRA.

In addition to adoptive cell therapy approaches aforementioned, our competitors are also investigating other cellbased approaches, including the potential of GammaDelta T-cell, CAR-Macrophages, CAR-NK cell, NK cell, NKT cell, CTLs, TILs, Marrow-infiltrating lymphocytes (MILs), Multi-tumor-associated antigen (TAA)-specific T-cells and virusspecific T-cells either preclinically or in a clinical setting (both hematologic malignancies and solid tumors). In this space there are a number of potential competitors, including, but not limited to: Achilles Therapeutics, Adicet Bio, Arsenal bio, Atara Bio, Aurora BioPharma, Cell Medica, Cellular Biomedicine Group Inc, CytomX, Celgene (now part of Bristol-Myers Squibb), Fate Therapeutics, Fortress Biotech, Gadeta (with Kite Pharma), Gamma Delta Therapeutics (with Takeda), Gamida cell, Genocea, Glycostem Therapeutics, iCell Gene Therapeutics, Immatics, Iovance Biotherapeutics (formerly Lion Bio), KSQ Therapeutics, MD Anderson Cancer Center, Multimmune, NantKwest, NexImmune, Nkarta, Sorrento Therapeutics, Marker Therapeutics, Tessa Therapeutics, TC Biopharm (with bluebird bio), Torque Therapeutics, Unum Therapeutics, WindMIL Therapeutics and Ziopharm Oncology. Although Immunocore is focused on soluble TCRs rather than engineered cell therapies, we could also face competition from Immunocore if it develops or acquires products directed at the same targets or indications as our TCR therapeutic product candidates. Moreover, many of our employees have come from a shared background within Immunocore and there is an awareness within Immunocore of certain of our confidential information on the technology platform controlled through confidentiality agreements. This knowledge could be used by Immunocore to facilitate its own developments or to target competitive products against our products placing it in a preferable position as compared to third party competitors.

The United Kingdom's withdrawal from the European Union could lead to increased market volatility, which could adversely impact the market price of our ADSs and make it more difficult for us to do business in Europe or have other adverse effects on our business.

The United Kingdom formally exited the European Union, commonly referred to as Brexit, on January 31, 2020. Under the terms of its departure, the United Kingdom will enter a transition period during which it will continue to follow all European Union rules and the trading relationship will remain the same. The transition period is scheduled to end on December 31, 2020. The long-term effects of Brexit will depend on the agreements and arrangements the United Kingdom negotiates with the European Union including whether and to what extent it will retain access to the European Union markets following the transition period. There will be a period of considerable uncertainty particularly in relation

to United Kingdom financial and banking markets as well as on the regulatory process in Europe as these negotiations continue to unfold. As a result of this uncertainty, financial markets could experience volatility which could adversely affect the market price of our ADSs. Depending on the final terms of the agreements and arrangements negotiated with the European Union, we may also face new regulatory costs and challenges that could have a material adverse effect on our operations, including the potential for a delay in our clinical progress and approvals in Europe. In particular, we could be subject to increased regulatory requirements in relation to the procurement, supply and transport of our end products, apheresis product used to manufacture end product and samples taken during clinical trials. There may be increased requirements for additional resources, procedures or licenses to facilitate the performance of our clinical trial protocols for example in relation to the release of our cell therapies, which are manufactured outside of the European Union, for use within the European Union. Given the uncertainty created by Brexit, we may find it more difficult to recruit and retain staff from the European Union and certain staff may choose to seek employment in other European Union countries rather than remain in the United Kingdom.

As a result of the foregoing developments, and in the absence of any clear indication that any agreement or arrangement with the European Union will contain a contrary requirement, we have already appointed our CROs to act as European Union legal representatives to act on our behalf in accordance with Article 19 of the European Union Clinical Trials Directive (Directive 2001/20/EC). We have also appointed quality representatives within the European Union to ensure our therapies can be released for use in the European Union in our clinical trials. Depending on the final terms of any agreements of arrangements there may be an impact on movement of goods between the European Union and the United Kingdom and additional requirements may apply prior to use of our products within the European Union.

Depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business worldwide more difficult. In addition, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue it could cause volatility in our financial results.

# Failure of our information technology systems could significantly disrupt the operation of our business.

Our ability to execute our business plan and to comply with regulators' requirements with respect to data control and data integrity, depends, in part, on the continued and uninterrupted performance of our information technology systems and similar systems used by third-party providers that we rely on. These systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information systems, sustained or repeated system failures or problems arising during the upgrade of any of our information systems that interrupt our ability to generate and maintain data, and in particular to operate our proprietary technology platform, could adversely affect our ability to operate our business. In addition, where disruption to such systems occurs at third-party providers, we may have limited ability to find alternative providers in any required timeframes or at all, and such disruption could significantly affect our ability to proceed with clinical or analytical or development programs.

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

Our operations and those of our third party suppliers and collaborators could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics, labor disputes or other business interruptions. While the company has business interruption insurance policies in place, any interruption could seriously harm our ability to timely proceed with any clinical programs or to supply SPEAR T-cells on a commercial basis or for use in clinical programs.

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

We conduct a significant portion of our operations within the United Kingdom 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 United Kingdom; 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.

# 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, 2019. 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.

# 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;

- 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 SPEAR 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 SPEAR T-cells, if approved for marketing, or price reductions;
- manufacture, supply or distribution shortages;
- 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, or 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; and
- changes in accounting principles.

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 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. In the event that it was necessary to regain compliance with this closing bid price requirement, we would be permitted 180 days in which to do so and would need to demonstrate that we had maintained a closing bid price of a minimum of \$1.00 per ADS for 10 consecutive business days. In the event that we were unable to regain compliance during this initial 180 day period, or a possible further 180 day period, we may need to implement reverse stock splits or change the ratio of ADSs to ordinary shares or take other measures in order to regain compliance with this closing bid price requirement. If we fail to continue to meet all applicable continued listing requirements for Nasdaq in the future and Nasdaq determines to delist our ADSs, the delisting could adversely affect the market liquidity of our ADSs and our ability to obtain financing to fund our operations.

# 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. Moreover, certain shareholders have rights under an investors rights agreement dated as of February 23, 2015, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. In addition, we have registered an aggregate of 151,248,915 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, 2019, an aggregate of 51,953,196 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 United States 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. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted and will adopt additional rules and regulations, such as mandatory "say on pay" voting requirements, that we must comply with. We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and 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. 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.

# 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. In addition, as a U.S. public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we assess the effectiveness of our disclosure controls and procedures and the effectiveness of our internal control over financial reporting at the end of each fiscal period. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting, and we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. 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 or 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 United States, and a substantial portion of our assets and all or a substantial portion of the assets of such persons are located outside the United States. 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 United States and the United Kingdom 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 United Kingdom 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 United Kingdom, 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 United States. In addition, awards for punitive damages in actions brought in the United States or elsewhere may be unenforceable in the United Kingdom. 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 United Kingdom 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 2. Properties

The following table summarizes the facilities we lease as of December 31, 2019, including the location and size of the facilities, and their primary use.

Location	Approximate Square Feet	Primary Usage	<b>Lease Expiration Dates</b>
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
Stevenage, Hertfordshire, United Kingdom	2,642	Administration	December 2023

As of December 31, 2019, all of the above sites were utilized by the Company with the exception of our facilities in Abingdon, Oxfordshire, of 46,017 sq ft, which are not currently occupied after completion of external works in November 2018.

We believe that our existing facilities are adequate for our near-term needs, but we expect to need additional space as we grow and expand our operations. We believe that suitable additional or alternative office, laboratory, and manufacturing space will be available as required in the future on commercially reasonable terms.

## Item 3. Legal Proceedings

As of December 31, 2019, 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

#### **Holders of Common Stock**

The Company's ADSs each represent six ordinary shares of Adaptimmune Therapeutics plc. The ADSs have been listed on Nasdaq since May 6, 2015 and are traded under "ADAP". As of February 24, 2020, there were approximately 26 holders of record of our ordinary shares, par value £0.001 per share, and approximately 10 holders of record of our ADSs. The closing sale price per ADS on Nasdaq on February 24, 2020 was \$3.58.

#### Dividends

Since our inception, we have not declared or paid any dividends on our ordinary shares. We intend to retain any earnings for use in our business and do not currently intend to pay dividends on our ordinary shares.

The payment of dividends by Adaptimmune Therapeutics plc is governed by English law. The declaration and payment of any future dividends will be at the discretion of our board of directors and will depend upon our results of operations, cash requirements, financial condition, contractual restrictions, restrictions imposed by our indebtedness, any future debt agreements or applicable laws and other factors that our board of directors may deem relevant.

# **Recent Sales of Unregistered Securities**

We did not sell any unregistered securities during the year ended December 31, 2019.

# **Information about Our Equity Compensation Plans**

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

# Item 6. Selected Financial Data

Not applicable because the Company is a smaller reporting company.

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

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with "Selected Financial Data" and the historical consolidated financial statements and the notes thereto included in "Financial Statements and Supplementary Data". Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect

to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

#### Overview

We are a clinical-stage biopharmaceutical company focused on providing novel cell therapies to people with cancer. We are a leader in the development of T-cell therapies for solid tumors.

Our proprietary SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables us to identify cancer targets, find and genetically engineer T-cell receptors ("TCRs") against those targets, and produce therapeutic candidates ("SPEAR T-cells") for administration to patients. Using our affinity engineered TCRs, we aim to become the first company to have a TCR T-cell approved for the treatment of a solid tumor indication.

# **Update on Clinical Pipeline Progress**

#### Wholly owned SPEAR T-cells

**ADP-A2M4—Multiple Indications:** Clinical trials are ongoing with our ADP-A2M4 SPEAR T-cell in multiple indications. In addition, planning is ongoing for initiation of a clinical trial combining ADP-A2M4 with a PD-1 / PD-L1 pathway inhibitor in 2020.

- A Phase 1 clinical trial in multiple tumor indications, namely urothelial, melanoma, head and neck, ovarian, NSCLC, esophageal and gastric cancers, synovial sarcoma and MRCLS completed enrollment in early 2020.
- A Phase 2 clinical trial has been initiated in synovial sarcoma and MRCLS. The trial will take place at sites in the United States, Canada and Europe. The trial will include up to 60 patients at a selected dose of up to 10 billion transduced ADP-A2M4 SPEAR T-cells. Primary responses will be assessed by overall response rate by RECIST v1.1. The lymphodepletion regimen will be fludarabine (30mg/m2/day) for 4 days and cyclophosphamide (600 mg/m2/day) for 3 days.
- A radiation sub-study under the Phase 1 clinical trial is continuing at the MD Anderson Cancer Center. The sub-study will treat up to 10 patients and has a primary endpoint of safety, with RECIST v1.1 responses being a secondary endpoint. The radiation is a low dose radiation and is administered to lesions or isocenters prior to lymphodepletion.

**ADP-A2AFP** - **Hepatocellular Carcinoma**: We continue dosing patients in our Phase 1, open-label, dose-escalation study designed to evaluate the safety and anti-tumor activity of our alpha fetoprotein ("AFP") therapeutic candidate for the treatment of hepatocellular carcinoma, or HCC. The trial is open in the United States, United Kingdom and the European Union. Patients are now enrolling in Cohort 3 and are being treated with target doses of 5 billion SPEAR T-cells (range 1.2 to 6 billion).

**ADP-A2M4CD8—SURPASS Trial:** Enrollment has started in a Phase 1 trial for a next generation SPEAR T-cell, ADP-A2M4CD8. This next generation SPEAR T-cell utilizes the same engineered T-cell receptor as ADP-A2M4, but with the addition of a CD8α homodimer. The addition of the CD8α homodimer has been shown in vitro to increase cytokine release and SPEAR T-cell potency. The SURPASS trial will enroll up to 30 patients across multiple solid tumor indications. Similar to our other trials, the SURPASS trial will include dose escalation.

*ADP-A2M10:* Two Phase 1 clinical trials were conducted with ADP-A2M10 for the treatment of (i) NSCLC, and (ii) urothelial, melanoma and head and neck cancers in the United States, Canada, the United Kingdom and Spain. Enrollment in these trials closed as planned in 2019.

# **Ongoing GSK Collaboration Agreement Programs**

The third target program under the Collaboration and License Agreement remains ongoing. GSK is currently entitled to nominate a fourth target program and, upon satisfying other conditions, may have the right to nominate a fifth program under the GSK Collaboration and License Agreement, in each case excluding our ongoing wholly-owned development programs.

#### Recent Events Since December 31, 2019

On January 13, 2020, the Company entered into a co-development and co-commercialization agreement with Astellas Pharma, Inc. (the "Astellas Collaboration Agreement"). The Company received an upfront payment of \$50.0 million in January 2020 under the agreement and will receive research funding of up to \$7.5 million per year from the start of research programs under the agreement. Additional milestones are possible under the agreement, but these are dependent on the success of the development and commercialization of research and products.

On January 24, 2020, the Company closed an underwritten public offering of 21,000,000 American Depository Shares (ADSs) which, together with the full exercise by the underwriters on February 7, 2020 of their option to purchase an additional 3,150,000 ADSs, generated net proceeds of approximately \$89.8 million.

#### **Financial Operations Overview**

#### New standards

On January 1, 2019, we adopted new accounting guidance on lease recognition, which has been codified within Accounting Standard Codification Topic 842, *Leases* ("ASC 842"). We adopted the guidance using the modified retrospective approach, with the cumulative effect of initially applying the guidance recognized as an adjustment to the opening balance of equity at January 1, 2019. Therefore, the comparative information for the year ended December 31, 2018 and as of December 31, 2018 has not been adjusted and continues to be reported under previous guidance. The effect on the accumulated deficit, total stockholders' equity and net assets as at January 1, 2019 was \$0. The adoption of ASC 842 has had a material impact on our financial statements. At January 1, 2019 we recognized right-of-use assets and liabilities for operating leases following the adoption date of \$22.2 million and \$26.9 million respectively and derecognized \$4.7 million of other liabilities and prepayments that had been recognized under previous guidance.

# Revenue

At December 31, 2019, the Company had one contract with a customer, which is the GSK Collaboration and License Agreement. The GSK Collaboration and License Agreement consists of multiple performance obligations. GSK nominated its third target under the Collaboration and License Agreement. The Company received \$3.2 million in 2019 following the nomination of the target and development of products to this target commenced in the year ended December 31, 2019. The development of products to the third target is a separate performance obligation. Revenue associated with this performance obligation is recognized as the development of products to the target progresses.

Future revenues will depend on the progress of the development programs within the Collaboration and License Agreement, GSK's progress with the NY-ESO program, and progress of development programs within the Astellas Collaboration Agreement, which are difficult to predict.

# Research and Development Expenses

Research and development expenses consist principally of the following:

- salaries for research and development staff and related expenses, including benefits;
- costs for production of compounds and drug substances for use in preclinical testing and clinical trials;

- 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 SPEAR
  T-cells for use in clinical trials;
- costs for clinical sites and patients
- costs to develop manufacturing capability at our U.S. facility for manufacture of SPEAR T-cells 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;
- amortization and depreciation of property, plant and equipment and intangible assets used to develop our SPEAR T-cells; and
- share-based compensation expenses;

#### offset by:

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

Research and development expenditures are expensed as incurred.

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. 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%. 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 the GSK Collaboration and License Agreement 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 12% of allowable R&D costs, which may result in a payable tax credit at an effective rate of approximately 9.7% of qualifying expenditure.

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 SPEAR T-cells 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 SPEAR T-cells for clinical trials.

For further detail please see Part I — Item 1A Risk Factors — Risks Related to the Development of our SPEAR T-cells of this Annual Report.

A change in the outcome of any of these variables may significantly change the costs and timing associated with the development of that SPEAR T cell. 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.

# General and Administrative Expenses

Our general and administrative expenses consist principally of:

- salaries for employees other than research and development staff, including benefits;
- business development expenses, including travel expenses;
- professional fees for auditors, lawyers and other consulting expenses;
- costs of facilities used for general and administrative use, communication, and office expenses;
- 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 in the United Kingdom and United States. Our revenue from the GSK Collaboration and License Agreement is denominated in pounds sterling and is generated by our U.K.-based subsidiary, which has a pounds sterling functional currency. As a result, these sales are subject to translation into U.S. dollars when we consolidate our financial statements. 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.

Until May 2018, our U.K. subsidiary with a pound sterling functional currency held our investments in marketable securities, which were predominately denominated in U.S. dollars. The entire change in the fair value of a foreign currency-denominated security, including the change due to foreign exchange, was included in other comprehensive income. At the end of May 2018, our investments in marketable securities were transferred from our

U.K. based subsidiary to the ultimate parent company, Adaptimmune Therapeutics plc, which reduced the potential for foreign exchange gains or losses arising on these investments.

Our 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. Since July 1, 2019, the foreign exchange gain or losses arising on the revaluation of intercompany loans of a long-term investment nature are reported within other comprehensive income (loss).

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 foreseeable expenses 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.

#### **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 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. Unsurrendered U.K. tax losses and tax credit carryforwards can be carried forward to be offset against future taxable profits, however this is restricted to an annual £5.0 million 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. There are accumulated tax loss carry forwards and tax credit carryforwards in the United Kingdom amounting to \$249.8 million and \$0.7 million as of December 31, 2019. These tax losses and tax credit carryforwards do not expire.

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 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% for the year ended December 31, 2019. Due to its activity in the United States, and the sourcing of its revenue, our U.S. subsidiary is not currently subject to any state or local income taxes.

We also benefit from tax credits arising through the Credit for Increasing Research Activities ("Research Tax Credit") under the U.S. Internal Revenue Code and the U.S. Orphan Drug Credit. There are accumulated tax credit carryforwards in the United States amounting to \$5.7 million as of December 31, 2019. These tax credit carryforwards expire after 20 years.

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.

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 Year Ended December 31, 2019 and 2018

The following table summarizes the results of our operations for the years ended December 31, 2019 and 2018, together with the changes to those items (in thousands):

		Year				
	December 31,					
		2019 2018		Increase/decrease		
Development revenue	\$	1,122	\$	20,391	\$ (19,269)	(94)%
License revenue		_		39,114	(39,114)	(100)%
Total revenue		1,122		59,505	(58,383)	(98)%
Research and development (including losses accrued on firm purchase commitments of \$5,000 and \$-)		(97,501)		(98,269)	768	(1)%
General and administrative expenses		(43,391)		(43,601)	210	(0)%
Total operating expenses		(140,892)		(141,870)	978	(1)%
Operating loss		(139,770)		(82,365)	(57,405)	<del>70</del> %
Interest income		2,772		2,849	(77)	(3)%
Other income (expense), net		75		(15,501)	15,576	(100)%
Loss before income taxes		(136,923)		(95,017)	(41,906)	44 %
Income taxes		(242)		(497)	255	(51)%
Loss for the period		(137,165)	\$	(95,514)	\$ (41,651)	44 %

#### Revenue

Revenue decreased by \$58.4 million to \$1.1 million in the year ended December 31, 2019 compared to \$59.5 million for the year ended December 31, 2018.

The revenue recognized for the year ended December 31, 2019 is due to development work of products to the third target nominated by GSK under the Collaboration and License Agreement. The development and license revenue for the year ended December 31, 2018 was recognized due to the performance under the NY-ESO transition program and the PRAME development plan, which were completed in 2018.

Future revenues will depend on the progress of the third target program, the development of programs for additional targets, and GSK's progress with the NY-ESO program, which are difficult to predict. We estimate that the remaining \$2.1 million of revenue from the \$3.2 million received following nomination of the third target should be recognized by the end of 2020 as development progresses.

## Research and development expenses

Research and development expenses decreased by \$0.8 million to \$97.5 million for the year ended December 31, 2019 from \$98.3 million for the year ended December 31, 2018. Our research and development expenses comprise the following (in thousands):

	Year Decem	ended ber 31.		
	2019	2018	Increase/de	ecrease
Salaries, materials, equipment, depreciation of property, plant and				
equipment and other employee-related costs <sup>(1)</sup>	\$ 63,240	\$ 60,590	\$ 2,650	4 %
Subcontracted expenditure	32,788	41,580	(8,792)	(21)%
Manufacturing facility expenditure	6,754	4,848	1,906	39 %
Accrued purchase commitments	5,000	_	5,000	NA
Share-based compensation expense	3,812	8,340	(4,528)	(54)%
Payments for in-process research and development	4,556	210	4,346	2,070 %
Reimbursements for research and development tax and expenditure				
credits and government grants	(18,649)	(17,299)	(1,350)	8 %
	\$ 97,501	\$ 98,269	\$ (768)	<u>(1)</u> %

<sup>(1)</sup> 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 \$0.8 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily due to the following:

- an increase of \$2.7 million in salaries, materials, equipment, depreciation of property, plant and equipment and
  other employee-related costs, due to a combination of factors including wage inflation, increased temporary
  staff costs, and an increase in the average number of employees engaged in research and development from 320
  to 322
- a decrease of \$8.8 million in subcontracted expenditures, including clinical trial expenses, contract research
  organization (CRO) costs and contract manufacturing expenses. This was primarily driven by a decrease in
  subcontracted expenses and clinical trial costs due to the transfer of NY-ESO to GSK in 2018
- an increase in expenditure of \$1.9 million on manufacturing due to increased activity at our U.S. facility in Philadelphia and the development of a dedicated vector manufacturing capability in Stevenage, Hertfordshire, United Kingdom
- an increase of \$5.0 million in accrued purchase commitments, which relate to the supply of the Dynabeads® CD3/CD28 technology. Management considered that there is sufficient uncertainty surrounding the future utility of the Dynabeads, which is dependent upon current clinical trial plans, the Company's clinical pipeline, manufacturing methods and undetermined future projects, to result in the purchase commitment being recognized in Research and Development expenses in the period. Further details of the purchase commitment can be found in Note 9 of the Consolidated Financial Statements.
- a decrease of \$4.5 million in share-based compensation expense due to forfeitures of share options
- an increase of \$4.3 million in payments for in-process research and development after entering into
  collaboration agreements relating to the development of next-generation SPEAR T-cell products with Alpine
  Immune Sciences, Inc. on May 14, 2019 and with Noile-Immune Biotech, Inc. on August 26, 2019; and

an increase in reimbursements for research and development tax and expenditure credits and government grants
of \$1.4 million due to an increase in eligible R&D expenditure and more costs falling within the UK SME
R&D scheme.

Our subcontracted costs for the year ended December 31, 2019 were \$32.8 million, compared to \$41.6 million in the same period of 2018, of which \$18.5 million related to process development for our SPEAR T-cell platform and the remaining \$14.3 million related to our wholly owned pipeline, including ADP-A2M4, ADP-A2M10 and ADP-A2AFP. Our research and development expenses are highly dependent on the phases and progression of our research projects and future clinical trial results and therefore fluctuate from period to period.

# General and administrative expenses

General and administrative expenses remained flat at \$43.4 million for the year ended December 31, 2019 compared to \$43.6 million in the same period in 2018. These expenses are not expected to vary as significantly expenses associated with the Company's other operating activities; however, the level of such expenses may vary with the success of the Company's clinical pipeline and any expansion of operations.

#### Interest income

Interest income was \$2.8 million for the year ended December 31, 2019 compared to \$2.8 million for the year ended December 31, 2018. Interest income primarily relates to interest on cash, cash equivalents and available-for-sale debt securities.

# Other income (expense), net

Other income (expense), net was income of \$0.1 million for the year ended December 31, 2019 compared to an expense of \$15.5 million for the year ended December 31, 2018. Other income (expense), 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. 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 gains or losses arising on the revaluation of intercompany loans of a long-term investment nature are reported within other comprehensive income (loss).

#### Income taxes

Income tax expense decreased to \$242,000 for the year ended December 31, 2019 from \$497,000 for the year ended December 31, 2018. Income taxes arise in the United States due to our U.S. subsidiary generating taxable profits. 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 GSK Collaboration and License Agreement, government grants and research and development tax and expenditure credits. From inception through to December 31, 2019, we have raised:

- \$513.8 million of proceeds from issues of equity, net of issue costs;
- \$151.4 million upfront fees, milestones and exercise fees under our GSK Collaboration and License Agreement;

- \$2.8 million of income in the form of government grants; and
- \$40.4 million in the form of U.K. research and development tax credits and receipts from the U.K. RDEC

  Scheme

We use a non-GAAP measure, Total Liquidity, which is defined as the total of cash and cash equivalents, short-term deposits 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".

On January 13, 2020, the Company entered into a co-development and co-commercialization agreement with Astellas Pharma Inc. The Company received an upfront payment of \$50.0 million in January 2020 under the agreement and will receive research funding of up to \$7.5 million per year. In addition, on January 24, 2020, the Company closed an underwritten public offering of 21,000,000 American Depository Shares (ADSs) which, together with the full exercise by the underwriters on February 7, 2020 of their option to purchase an additional 3,150,000 ADSs, generated net proceeds of approximately \$89.8 million.

As of December 31, 2019, we had cash and cash equivalents of \$50.4 million and Total Liquidity of \$89.5 million. We believe that our Total Liquidity, combined with the upfront payment and the recently completed public offering of ADSs described above, will be sufficient to fund our operations, based upon our currently anticipated research and development activities and planned capital spending, into the second half of 2021.

During the year ended December 31, 2019, the Company incurred a net loss of \$137.2 million, used cash of \$112.5 million in its operating activities, and generated revenues of \$1.1 million. The Company has incurred net losses in most periods since inception, and it expects to incur operating losses in foreseeable future periods.

Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued.

#### Cash Flows

The following table summarizes the results of our cash flows for the years ended December 31, 2019 and 2018 (in thousands).

		Year ended December 31,			
	2019			2018	
Net cash used in operating activities	\$	(112,507)	\$	(104,388)	
Net cash provided by (used in) investing activities		94,945		(17,457)	
Net cash provided by financing activities		366		102,690	
Cash, cash equivalents and restricted cash		54,908		72,476	

## **Operating Activities**

Year ended December 31, 2019 compared to December 31, 2018

Net cash used in operating activities increased by \$8.1 million to \$112.5 million for the year ended December 31, 2019 from \$104.4 million for the year ended December 31, 2018. Net cash used in operating activities is significantly impacted by the timing of milestone payments received from GSK under the GSK Collaboration and License Agreement. In the year ended December 31, 2019, we received \$3.2 million of milestone payments from GSK compared to \$30.2 million in the year ended December 31, 2018. Excluding cash inflows from the GSK milestone payments and the associated VAT, the cash used in operations decreased in the year ended December 31, 2019. This was primarily due to higher subcontracted expenditure being incurred in 2018 under the GSK Collaboration Agreement.

# Components of cash flows from operating activities

Net cash used in operating activities of \$112.5 million for the year ended December 31, 2019 comprised a net loss of \$137.2 million offset by \$4.7 million of favorable changes in operating assets and liabilities and noncash items of \$20.0 million. The noncash items consisted primarily of depreciation expense on plant and equipment of \$7.2 million, amortization of intangibles of \$0.8 million, share-based compensation expense of \$11.1 million, and unrealized foreign exchange losses of \$1.1 million.

Net cash used in operating activities of \$104.4 million for the year ended December 31, 2018 comprised a net loss of \$95.5 million and \$45.3 million of adverse changes in operating assets and liabilities offset by noncash items of \$36.5 million. The noncash items consisted primarily of depreciation expense on plant and equipment of \$7.2 million, share-based compensation expense of \$16.2 million and a realized loss on marketable securities of \$2.5 million and unrealized foreign exchange losses of \$9.7 million.

## **Investing Activities**

Net cash provided by investing activities was \$94.9 million for the year ended December 31, 2019 compared to net cash used in investing activities of \$17.5 million for the year ended December 31, 2018.

Net cash provided by investing activities in the year ended December 31, 2019 included purchases of property and equipment of \$1.6 million, acquisition of intangibles of \$1.5 million, investment in marketable securities with maturities greater than three months but less than 12 months of \$27.3 million, offset by cash inflows from maturity or redemption of marketable securities with maturities greater than three months but less than 12 months of \$125.3 million. The Company invests surplus cash and cash equivalents in marketable securities. In the year ended December 31, 2019, the investments in marketable securities were reduced to fund the Company's ongoing operations.

Net cash used in investing activities in the year ended December 31, 2018, included purchases of property and equipment of \$3.9 million, acquisition of intangibles of \$0.8 million, and investment in marketable securities with maturities greater than three months but less than 12 months of \$150.8 million, offset by cash inflows from maturity or redemption of marketable securities with maturities greater than three months but less than 12 months of \$138.0 million. In the year ended December 31, 2018, the Company invested surplus cash, including net proceeds from issuance of shares in marketable securities.

#### Financing Activities

Net cash provided by financing activities was \$0.4 million and \$102.7 million for the years ended December 31, 2019 and 2018, respectively.

Net cash provided by financing activities for the year ended December 31, 2019 consisted of proceeds from exercise of share options of \$0.4 million. As disclosed previously, the Company completed a successful equity offering in January 2020.

Net cash provided by financing activities for the year ended December 31, 2018 consisted of \$99.7 million net of issuance costs of \$0.3 million, raised through a registered direct offering in September 2018 and proceeds from exercise of share options of \$3.0 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):

	Dec	December 31,		December 31,	
		2019		2018	
Cash and cash equivalents	\$	50,412	\$	68,379	
Marketable securities		39,130		136,755	
Total Liquidity	\$	89,542	\$	205,134	

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 liquidity, financial flexibility, capital structure and leverage. The definition of Total Liquidity includes marketable securities, which are highly liquid and available to use in our current operations.

#### **Off-Balance Sheet Arrangements**

During the periods presented, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC other than operating leases as described in Note 9 of the consolidated financial statements included in Item 15 of this Annual Report.

# **Contractual Obligations**

Operating lease obligations

Operating lease obligations primarily consists of minimum lease payments under non-cancellable leases for laboratory and office property in Oxfordshire, United Kingdom, and Philadelphia, United States.

In May 2017, we entered into an agreement for the lease of a building at Milton Park, Oxfordshire, United Kingdom. The lease term expires on October 23, 2041, with termination options exercisable by us on the fifth anniversary of the lease commencement date and at approximately five yearly intervals thereafter.

# Purchase obligations

Purchase obligations include signed orders for capital equipment, clinical materials and contract manufacturing, which have been committed but not yet received and committed funding under the MD Anderson strategic alliance. The timing of the payments may vary depending on the rate of progress of development and clinical trial enrollment rates. Future clinical trial expenses 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.

On September 26, 2016, we announced that we had 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 are collaborating on a number of studies including clinical and preclinical development of our SPEAR T-cell therapies targeting NY-ESO and MAGE-A10 and we will collaborate on future clinical stage first and second generation SPEAR T-cell therapies such as ADP-A2M4 across a number of cancers, including bladder, lung, ovarian, head and neck, melanoma, synovial sarcoma, esophageal and gastric cancers. Under the terms of the agreement, we committed at least \$19.6 million to fund studies. The Company made an upfront payment of \$3,412,000 to MD Anderson in the year ended December 31, 2017 and milestone payments of \$2,325,000 in the year ended December 31, 2018. Payment of this funding is contingent on mutual agreement to study orders under the alliance agreement and the performance of set milestones by MD Anderson. The timing and amount of future payments is uncertain.

On June 16, 2016, we entered into a supply agreement with ThermoFisher for the supply of the Dynabeads® CD3/CD28 technology. The Dynabeads® CD3/CD28 technology is designed to isolate, activate and expand human T-cells, and is being used in the manufacturing of our affinity enhanced T-cell therapies. The supply agreement runs until December 31, 2025. Under the supply agreement, we are required to purchase our requirements for CD3/CD28 magnetic

bead product exclusively from ThermoFisher for a period of five years and there are also minimum purchasing obligations (which have been included in the purchase obligations above). ThermoFisher has the right to terminate the supply agreement for material breach or insolvency. There are minimum purchasing obligations of \$5.0 million, \$2.5 million of which payable in 2020 and \$2.5 million of which is payable in 2021, and Adaptimmune has recognized these commitments within Research and development expense in the Statement of operations for the year ended December 31, 2019 (further details of this are provided in Note 9 of the Financial Statements).

#### Other obligations

On August 26, 2019, we entered into a collaboration and license agreement relating to the development of next-generation SPEAR T-cell products with Noile-Immune Biotech Inc ("Noile-Immune"). 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 royalties on net sales of resulting products.

On May 14, 2019, we entered into a Collaboration Agreement relating to the development of next-generation SPEAR T-cell products with Alpine Immune Sciences Inc ("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. Alpine would also receive low single-digit royalties on worldwide net sales of applicable products.

On November 25, 2015, we entered into a Research Collaboration and License Agreement relating to gene editing and HLA-engineering technology with Universal Cells. We paid an upfront license fee of \$2.5 million to Universal Cells. A milestone payment of \$3.0 million was made in February 2016 and further milestone payments of \$0.2 million and \$0.9 million were made in the year ended December 31, 2018 and 2017, respectively. The agreement was amended and re-stated as at January 13, 2020, primarily to reflect changes to the development plan agreed between the parties. Further milestone payments of up to \$38.4 million if certain development and product milestones are achieved. Universal Cells would also receive a profit-share payment for the first product, and royalties on sales of other products utilizing its technology.

In 2012, we entered into a series of license and sub-license agreements with Life Technologies Corporation, part of ThermoFisher that provide us with a field-based exclusive license under certain intellectual property rights owned or controlled by ThermoFisher. We paid upfront license fees of \$1.0 million relating to the license and sublicense agreements and are obligated to pay minimum annual royalties (in the tens of thousands of U.S. dollars prior to licensed product approval and thereafter at a level of 50% of running royalties in the previous year), milestone payments and a low single-digit running royalty payable on the net selling price of each licensed product.

# Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our consolidated financial statements in accordance with U.S. GAAP. Our preparation of these 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.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

# Revenue Recognition

The Company has one contract with a customer, which is the GSK Collaboration and License Agreement. The GSK Collaboration and License Agreement consists of multiple performance obligations, including the transition of the NY-ESO SPEAR T-cell program to GSK, the development of a second target, PRAME, the NY-ESO License, and following its nomination in 2019, a third target under the Agreement.

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. In estimating the amount of variable consideration to be included in the transaction price, the Company considers the latest project plan and other available information. 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.

The determination of whether future milestones are probable requires significant judgment and the impact of a change in the determination of whether a milestone is probable is recognized in the period the judgment is revised. This can significantly impact the revenue recognized. In the year ended December 31, 2018, revenue of \$10.4 million, was recognized due to development milestones becoming probable in the period. No significant changes to this assessment of the probability of further milestones being met in relation to GSK's development of NY-ESO occurred during the year ended December 31, 2019. As the development program progresses and the uncertainties underlying the milestones resolve, further milestones may become probable.

Upfront payments are allocated between the performance obligations using the Company's best estimate of the relative selling price of each performance obligation. The best estimate of the selling price is determined after 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. The variable consideration is allocated to the performance obligation to which it relates.

The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligation. The Company satisfied the performance obligations relating to the transition of the NY-ESO SPEAR T-cell program and the development of a second target, PRAME, over time 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 NY-ESO transition and the PRAME pre-clinical development program were completed in 2018.

The performance obligation relating to the NY-ESO License was recognized at a point-in-time, upon commencement of the license in September 2018.

In 2019, GSK has nominated its third target under the Collaboration and License Agreement. Development of products to this target commenced in the year ended December 31, 2019, and the Company received \$3.2 million following the nomination of the target. The development of products to the third target is a separate performance obligation, for which revenue expected to be recognized by the end of 2020 as the development progresses. \$1.1 million of revenue related to this target was recognized in the year ended December 31, 2019. Future revenues will depend on the progress of the development programs within the Collaboration and License Agreement, and GSK's progress with the NY-ESO program, which are difficult to predict.

# **Clinical Trial Expenses**

Expenses related to clinical trials are recognized as services are received. Nonrefundable advance payments for services are deferred and recognized in the 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.

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We may confirm the accuracy of our estimates with the applicable service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to: CROs in connection with clinical trials; operators of investigative sites in connection with clinical trials; vendors in connection with preclinical development activities; and vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid amount accordingly.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. For example, the strategic alliance with MD Anderson involves milestone payments made in advance of the service being provided. In recognizing the expense, we estimate the cost by patient enrolled and recognize this over the period between initial dosing and estimated cessation of patient monitoring activities. The duration of the clinical trial is estimated based on internal historical data and projections. There is limited data available and our estimate of the duration of the clinical may vary as we obtain further data.

Although we do not expect our estimates of the amounts, status and timing of services performed to be materially different from the actual amounts, status and timing of services performed, if they do vary, we may report amounts that are too high or too low in any particular period. To date, there has been no material difference between our estimates and the amount actually incurred.

## 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 clinical materials with alternative future use consist of Dynabeads® CD3/CD28 technology ("Dynabeads"), which is designed to isolate, activate and expand human T-cells, and is being used in the manufacturing of the Company's affinity enhanced T-cell

therapies. The Dynabeads are purchased under a supply agreement, which runs until December 31, 2025. The supply agreement includes minimum purchasing obligations.

As of December 31, 2019, we have \$4.0 million of clinical materials, of which we expect to consume \$1.5 million within the next 12 months and the remaining amount over the next several years. At each reporting date, we consider whether the Dynabeads on-hand and committed purchase obligations are impaired due to excess quantity over current forecast demand by considering manufacturing forecasts, forecasts of clinical trial enrollments, stability testing results, technological developments and future development programs. There are minimum purchasing obligations of \$5.0 million, \$2.5 million of which payable in 2020 and \$2.5 million of which is payable in 2021. Management regularly updates the assessment of the utility of the Dynabeads, and in the year ended December 31, 2019, considers that there is sufficient uncertainty surrounding the utility of the Dynabeads, which is dependent upon current study trajectories, the Company's clinical pipeline, manufacturing methods and undetermined future projects, to result in the \$5.0 million purchase commitment being recognized in Research and development.

# **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 we have no external borrowings, 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.

# U.K. R&D Tax and Expenditure Credits

Research and development expenditure is presented net of reimbursements from the U.K. Small and Medium-sized Entity R&D Tax Credit Scheme and the U.K. Research and Development Expenditure Credit Scheme. Reimbursable tax and expenditure credits are recognized when it is probable that the Company has complied with any attached conditions and will receive the reimbursement. Management is required to develop estimates at each reporting date on the amount of the reimbursable tax and expenditure credits, which includes an estimate of qualifying expenditure. The tax and expenditure credits are claimed from Her Majesty's Revenue and Customs ("HMRC") as part of the annual U.K. tax return. Although, we do not expect our estimates to be materially different from amounts claimed and subsequently reimbursed by HMRC, if our estimates of the qualifying expenditure differ from the amount claimed, we may report amounts that are too high or too low in any particular period. To date, there has been no material differences between our estimates and the amount actually reimbursed.

# U.S. Research Tax Credits and Orphan Drug Credit

In 2018, the Company estimated that it would benefit from Research Tax Credits and Orphan Drug Credits of \$2.0 million for the year ended December 31, 2018, of which \$0.7 million would offset taxes in the year ended December 31, 2018. As of December 31, 2019, the Company estimated that it will benefit from Research Tax Credits and Orphan Drug Credits of \$1.8 million for the year ended December 31, 2019, of which \$0.6 million will offset taxes in the year ended December 31, 2019. Although we do not expect our estimates to be materially different from amounts claimed, if our estimates of the qualifying expenditure differ from the amount claimed, we may report amounts that are too high or too low in any particular period.

## **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, 2019, we have deferred tax assets of \$62.9 million, offset by deferred tax liabilities of \$3.7 million and a valuation allowance of \$59.2 million.

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.

The U.S. subsidiary 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. In determining whether the deferred tax asset is more-likely-than-not of being recognized, the Company has taken into account the short 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 predominately in 2020 and beyond. 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 the U.S. subsidiary. Less weight has been given to forecasts of taxable income beyond the next few years. The deferred tax asset arising in the United States is only considered more-likely-than-not of being realized to the extent that there are available reversing temporary taxable differences. 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 the U.S. subsidiary.

# **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 is measured at the grant-date fair value of the award and recognized as an expense over the requisite service period, for those awards that are ultimately expected to vest. 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.

# **Valuation of Share Options**

The Black-Scholes option pricing model requires the input of assumptions, including share price volatility, the expected term of a share option, the risk free rate and the underlying share valuation. The assumption of the expected term of share options involves management judgment. We estimate that the expected life of our share options, which is the time from the grant date to the expected exercise date, is five years. 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.

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

Smaller reporting companies are not required to provide information in response to this item under Item 10(f) of Regulation S-K, Securities Act Rule 405, Exchange Act Rule 12b-2 and Rule 3-05 of Regulation S-X.

#### Item 8. Supplementary financial information

Smaller reporting companies are not required to provide information in response to this item under Item 10(f) of Regulation S-K, Securities Act Rule 405, Exchange Act Rule 12b-2 and Rule 3-05 of Regulation S-X.

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

None

## Item 9A. Controls and Procedures

### **Disclosure Controls and Procedures.**

Our management, with the participation of our Chief Executive Officer and Interim 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 Interim Chief Financial Officer have concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive and Interim Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

### 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 reasonably assurance of achieving their control objectives. Under the supervision and with the participation of our management, including our Chief Executive Officer and Interim 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. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

KPMG, LLP, the independent registered public accounting firm who audited the Company's Consolidated Financial Statements included in this Form 10-K, has issued a report on the Company's internal control over financial reporting, which is included in Item 15 of this Form 10-K.

# Changes in Internal Control Over Financial Reporting.

There has been no 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 2019 that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

In January 2019, the Company has adopted new guidance on lease accounting, which has been codified within Accounting Standard Codification Topic 842, *Leases* ("ASC 842"). As a consequence of the new guidance, the Company has implemented several new internal controls.

#### Item 9B. Other Information

None

#### 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, 2019.

#### **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, 2019.

# 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, 2019.

# 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, 2019.

### **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, 2019.

# **PART IV**

# Item 15. Exhibits, 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.

# 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:

Exhibit Number	Description of Exhibit
3.1*	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)
4.1*	Form of certificate evidencing ordinary shares (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form F-1 (file no: 333-203267)).
4.2*	Form of Deposit Agreement among Adaptimmune Therapeutics plc, Citibank, N.A., as the depositary bank and Holders and Beneficial Owners of ADSs issued thereunder (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form F-1 (file no: 333-203267)).
4.3*	Form of American Depositary Receipt (included in Exhibit 4.2) (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form F-1 (file no: 333-203267)).
4.4**	Description of the Registrant's Securities.
10.1*†	Collaboration Agreement, dated January 5, 2018, between Adaptimmune Limited and Cell Therapy Catapult Limited (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).
10.2*†	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).
10.3*†	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).
10.4**††	<u>Collaboration and License Agreement, dated January 13, 2020, by and between Universal Cells, Inc. and Adaptimmune Limited.</u>
10.5**††	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.
10.6**††	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.
10.7*†	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 10-Q filed with the SEC on August 8, 2016).
10.8*†	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).

Exhibit Number	Description of Exhibit
10.9*	Employment Agreement dated as of January 13, 2020 by and between Adaptimmune, LLC and Elliot Norry (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on January 13, 2020).
10.10*	<u>Senior Vice President Severance Policy dated December 4, 2019 (incorporated by reference to Exhibit 10.2 to our Form 8 K filed with the SEC on January 13, 2020).</u>
10.11*	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).
10.12*	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 26, 2019).
10.13*	<u>James Noble Letter Agreement dated June 26, 2019 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on June 26, 2019).</u>
10.14*	<u>James Noble Variation Agreement dated June 26, 2019 (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on June 26, 2019).</u>
10.15*	<u>James Noble Letter of Appointment dated June 26, 2019 (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the SEC on June 26, 2019).</u>
10.16*	<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>
10.17*	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).
10.18*	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).
10.19*	Executive Severance policy of Adaptimmune Therapeutics plc, dated March 10, 2017, and effective March 10, 2017 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 13, 2017).
10.20*	<u>Letter of Appointment, dated May 23, 2016 and effective June 23, 2016, between the Company and Barbara Duncan (incorporated by reference to Exhibit 99.1 to our Form 8-K filed with the SEC on June 23, 2016).</u>
10.21*	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).

Exhibit Number	Description of Exhibit
10.22*	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).
10.23*	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).
10.24*	Letter of Appointment, dated August 9, 2016 and effective August 11, 2016, between the Company and Elliott Sigal (incorporated by reference to Exhibit 10.5 to our Form 8-K filed with the SEC on August 12, 2016).
10.25*	Letter of Appointment, dated October 26, 2016 and effective November 1, 2016, between the Company and Giles Kerr (incorporated by reference to Exhibit 10.7 to our Form 10-Q filed with the SEC on November 10, 2016).
10.26*	Letter of Appointment, dated November 7, 2016 and effective November 14, 2016, between the Company and Tal Zaks (incorporated by reference to Exhibit 10.8 to our Form 10-Q filed with the SEC on November 10, 2016).
10.27*	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 the Company's Transition Report on Form 20-F filed with the SEC on March 17, 2016).
10.28*	Adaptimmune Therapeutics plc 2015 Share Option Scheme, dated March 16, 2015, as amended on April 15, 2015, January 13, 2016 and December 18, 2017 (incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).
10.29*	Adaptimmune Therapeutics plc 2016 Employee Share Option Scheme, dated January 14, 2016, as amended on December 18, 2017 (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).
10.30*	Adaptimmune Limited Share Option Scheme (Incorporating Management Incentive Options), as amended on January 13, 2016 (incorporated by reference to Exhibit 4.28 to the Company's Transition Report on Form 20-F filed with the SEC on March 17, 2016).
10.31*	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 the Company's Transition Report on Form 20-F filed with the SEC on March 17, 2016).
10.32*	Adaptimmune Limited Company Share Option Plan, dated December 16, 2014, as amended on January 13, 2016 (incorporated by reference to Exhibit 4.30 to the Company's Transition Report on Form 20-F filed with the SEC on March 17, 2016).

Exhibit Number	Description of Exhibit
10.33*	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 the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018).
10.34*	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 the Company's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 15, 2018)
10.35*	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).
10.36*	<u>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 the Company's Transition Report on Form 20-F filed with the SEC on October 13, 2015).</u>
10.37*†	Amendment Agreement No. 6, dated July 20, 2018 between Adaptimmune Limited and GlaxoSmithKline Intellectual Property Development Ltd. (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on August 2, 2018).
10.38*†	Amendment Agreement No. 5, dated September 7, 2017 between Adaptimmune Limited and GlaxoSmithKline Intellectual Property Development Ltd. (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on November 2, 2017).
10.39*†	Amendment Agreement No. 2, dated February 2, 2016 between Adaptimmune Limited and GlaxoSmithKline Intellectual Property Development Ltd (incorporated by reference to Exhibit 4.4 to the Company's Transition Report on Form 20-F filed with the SEC on March 17, 2016).
10.40*†	Amendment Agreement No. 1, dated May 8, 2015 between Adaptimmune Limited and GlaxoSmithKline Intellectual Property Development Ltd (incorporated by reference to Exhibit 4.3 to the Company's Transition Report on Form 20-F filed with the SEC on March 17, 2016).
10.41*†	Collaboration and License Agreement, dated May 30, 2014 between Adaptimmune Limited and GlaxoSmithKline Intellectual Property Development Ltd (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (file no: 333-203267)).
14.1*	Code of Business Conduct and Ethics of Adaptimmune Therapeutics plc (incorporated by reference to Exhibit 14.1 to our Form 8-K filed with the SEC on July 20, 2017).
21.1*	<u>List of Subsidiaries (incorporated by reference to Exhibit 21.1 to our Registration Statement on Form F-1 (file no: 333-203267)).</u>
23.1**	Consent of KPMG LLP
31.1**	Certificate of Chief Executive Officer pursuant to 17 CFR 240.13a-14(a).
31.2**	Certificate of Chief Financial Officer pursuant to 17 CFR 240.13a-14(a).
32.1**	Certificate of Chief Executive Officer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C.1350.

Exhibit Number	Description of Exhibit
32.2**	Certificate of Chief Financial Officer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C.1350.
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.
101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104**	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

<sup>\*</sup> Previously filed.

# Item 16. Form 10-K Summary

None.

<sup>\*\*</sup> Filed herewith.

<sup>†</sup> 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.
†† Confidential treatment is being sought with respect to portions of this exhibit, which has been filed separately with the

<sup>††</sup> Confidential treatment is being sought with respect to portions of this exhibit, which has been filed separately with the Securities and Exchange Commission. The confidential portions of this exhibit have been omitted and are marked by asterisks.

#### **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, in Oxfordshire, England, on February 27, 2020.

# 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 Michael Garone, 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 February 27, 2020, in the capacities indicated.

Signature	Title	Date
/s/ Adrian Rawcliffe Adrian Rawcliffe	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2020
/s/ Michael Garone Michael Garone	Interim Chief Financial Officer (Principal Accounting and Financial Officer)	February 27, 2020
/s/ David M. Mott David M. Mott	Chairman of the Board of Directors	February 27, 2020
/s/ Lawrence M. Alleva Lawrence M. Alleva	Director	February 27, 2020
/s/ Ali Behbahani, MD Ali Behbahani, MD	Director	February 27, 2020
/s/ Barbara Duncan Barbara Duncan	Director	February 27, 2020
/s/John Furey John Furey	Director	February 27, 2020
/s/ Giles Kerr Giles Kerr	Director	February 27, 2020
/s/ James Noble James Noble	Director	February 27, 2020
/s/ Elliott Sigal, MD, PhD Elliott Sigal, MD, PhD	Director	February 27, 2020
/s/ Tal Zaks, MD, PhD Tal Zaks, MD, PhD	Director	February 27, 2020

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

# To the Stockholders and Board of Directors 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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in equity, and cash flows for each of the years in the two-year period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 27, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

# Change in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standard Codification Topic 842, Leases, and changed its method of accounting for revenue from contracts with customers as of January 1, 2018 due to the adoption of Accounting Standard Codification Topic 606, Revenue from Contracts with Customers.

#### 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 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. 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

The critical audit matters communicated below 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. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

# Evaluation of the incremental borrowing rates used to measure the right-of-use assets and operating lease liabilities upon adoption of ASC Topic 842.

As discussed in Note 2 and Note 8 to the consolidated financial statements, the Company recorded operating lease right-of-use (ROU) assets and operating lease liabilities of \$22.2 million and \$26.9 million, respectively, at January 1, 2019. The rate implicit in the lease is not readily determinable, therefore, the Company uses incremental borrowing rates to measure the present value of lease payments. The incremental borrowing rates are developed using information on indicative borrowing rates adjusted for company and market specific factors.

We identified the evaluation of incremental borrowing rates used to measure ROU assets and operating lease liabilities upon adoption of ASC Topic 842 as a critical audit matter. It required especially challenging auditor judgement and specialized skills and knowledge to assess the incremental borrowing rates since the company does not have any external borrowings.

The primary procedures we performed to address this critical audit matter included the following.

We involved valuation professionals with specialized skills and knowledge, who assisted in:

- Evaluating the Company's indicative borrowing rate by comparing it to a borrowing rate independently developed using publicly available market data for comparable entities, and
- Developing a synthetic credit rating which was adjusted for market data of comparable companies to
  determine an independent range of incremental borrowing rates. The synthetic credit rating approach
  compared financial ratios of the Company to the ratios of other comparable public companies with
  established credit ratings. The model determined a median value for each financial ratio at each credit
  rating and then a simple average score for each financial ratio was calculated to determine a range of
  overall credit ratings.

We performed sensitivity analyses by comparing the Company's incremental borrowing rates to that of the independently developed range noted above to evaluate the impact on the Company's measurement of the ROU assets and operating lease liabilities

# Evaluation of clinical materials and related committed purchase obligation impairment analysis

As discussed in Notes 2, 5, and 10 to the consolidated financial statements, the Company has clinical materials of \$4.0 million as of December 31, 2019 and a related accrued purchase commitments of \$5.0 million, of which \$2.5 million is payable in 2020 and \$2.5 million is payable in 2021. The Company assesses the clinical materials and related committed purchase obligations for impairment at each reporting date and whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable, considering the on-hand materials and committed purchase obligations. During the year ended December 31, 2019 the Company recognized \$5.0 million of accrued purchase commitments and research and development expense relating to the uncertainty surrounding the utilisation of clinical materials.

We identified the evaluation of clinical materials and related committed purchase obligations impairment analysis as a critical audit matter. A high degree of auditor judgement was required in assessing the Company's assumptions within the manufacturing forecasts relating to the shelf life of clinical materials and forecasts of clinical trial enrollments used to estimate future clinical material utilization.

The primary procedures we performed to address this critical audit matter included the following:

• We tested certain internal controls over the Company's process for assessing the impairment of clinical materials and committed purchase obligations, including controls over the development of assumptions listed above to estimate future clinical material utilization.

- We evaluated the Company's ability to accurately estimate the clinical material utilization by comparing historically estimated future utilization to actual results.
- We assessed the assumptions, listed above, in the impairment analysis through a combination of inquiry of finance and operations personnel and inspection of manufacturing budgets to assess the impact of clinical trial enrollment, current quantities on hand, and forecasted future demand of clinical materials.
- We examined the Company's assumption of shelf life of the clinical materials into the manufacturing forecasts by obtaining third party confirmations of stability testing results.
- We performed sensitivity analyses of the clinical trial enrollments and the timeline to utilize the clinical materials to evaluate their impact on the Company's clinical material impairment analysis.

/s/ KPMG LLP

We have served as the Company's auditor since 2010.

KPMG LLP

Reading, United Kingdom February 27, 2020

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control Over Financial Reporting

We have audited Adaptimmune Therapeutics plc and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in equity, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements), and our report dated February 27, 2020 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls

may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

Reading, United Kingdom February 27, 2020

# ADAPTIMMUNE THERAPEUTICS PLC CONSOLIDATED BALANCE SHEETS (in thousands, except share data)

	De	ecember 31, 2019	De	cember 31, 2018
Assets	' <u></u>			
Current assets				
Cash and cash equivalents	\$	50,412	\$	68,379
Marketable securities - available-for-sale debt securities		39,130		136,755
Accounts receivable, net of allowance for doubtful accounts of \$0 and \$0		_		192
Other current assets and prepaid expenses (including current portion of clinical				
materials)		30,947		25,769
Total current assets	_	120,489		231,095
		.,		,,,,,
Restricted cash		4,496		4,097
Clinical materials		2,503		3,953
Operating lease right-of-use assets, net of accumulated amortization		20,789		_
Property, plant and equipment, net of accumulated depreciation		31,068		36,118
Intangibles, net of accumulated amortization		2,198		1,473
Total assets	\$	181,543	\$	276,736
Total about	Ě		_	
Liabilities and stockholders' equity				
Current liabilities				
Accounts payable		6,357		4,083
Operating lease liabilities, current		2,493		4,005
Accrued expenses and other accrued liabilities		23,363		20,354
Deferred revenue		2,128		20,334
Total current liabilities	_	34,341	_	24,437
Total current natinues		34,341		24,437
Operating lease liabilities, non gurrent		22,966		
Operating lease liabilities, non-current Other liabilities, non-current		598		5,414
Total liabilities			_	
Total nathrities		57,905		29,851
Caralda Idana and an atan				
Stockholders' equity  Common stock - Ordinary shares partially 50 001 705 057 300 authorized and				
Common stock - Ordinary shares par value £0.001, 785,857,300 authorized and				
631,003,568 issued and outstanding (2018: 701,103,126 authorized and		943		939
627,454,270 issued and outstanding)				
Additional paid in capital		585,623		574,208
Accumulated other comprehensive loss Accumulated deficit		(7,264)		(9,763)
	_	(455,664)		(318,499)
Total stockholders' equity		123,638		246,885
m - 11/100-1 - 1 - 11/11 - 1	d.	101 542	ф.	250 520
Total liabilities and stockholders' equity	\$	181,543	\$	276,736

# ADAPTIMMUNE THERAPEUTICS PLC CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except share and per share data)

		Year ended December 31,			
		2019		2018	
Development revenue		1,122		20,391	
License revenue				39,114	
Total revenue	\$	1,122	\$	59,505	
Operating expenses					
Research and development		(97,501)		(98,269)	
(including losses accrued on firm purchase commitments of \$5,000 and \$-)		(37,301)		(30,203)	
General and administrative		(43,391)		(43,601)	
Total operating expenses		(140,892)		(141,870)	
Operating loss		(139,770)		(82,365)	
Interest income		2,772		2,849	
Other income (expense), net		75		(15,501)	
Loss before income taxes		(136,923)		(95,017)	
Income tax expense		(242)		(497)	
Net loss attributable to ordinary shareholders	\$	(137,165)	\$	(95,514)	
V				<u> </u>	
Net loss per ordinary share - Basic and diluted					
Basic and diluted	\$	(0.22)	\$	(0.16)	
		` ,		Ì	
Weighted average shares outstanding:					
Basic and diluted	(	529,805,218		584,338,942	

# ADAPTIMMUNE THERAPEUTICS PLC CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (in thousands)

	Year o Deceml	 =
	2019	2018
Net loss	\$ (137,165)	\$ (95,514)
Other comprehensive (loss) income, net of tax		
Foreign currency translation adjustments, net of tax of \$0 and \$0	(9,478)	8,260
Foreign currency gains on intercompany loan of a long-term investment nature, net of tax		
of \$0 and \$0	11,783	_
Unrealized (gains) losses on available-for-sale debt securities		
Unrealized holding gains on available-for-sale debt securities, net of tax of \$0 and \$0	207	1,145
Reclassification adjustment for (gains) losses on available-for-sale debt securities		
included in net loss, net of tax of \$0 and \$0	(13)	2,473
Total comprehensive loss for the period	\$ (134,666)	\$ (83,636)

# ADAPTIMMUNE THERAPEUTICS PLC CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (in thousands, except share data)

Accumulated other income	
Accumulated	
Accumulated unrealized	
foreign gains (losses)	T-4-1
currency on available-for- Common Common Additional translation sale debt Accumulated	Total stockholders'
stock stock paid in capital adjustments securities deficit	equity
Balance as of January 1, 2018 562,119,334 854 455,401 (17,867) (3,774) (231,630)	202,984
Cumulative effects of applying	
new accounting standards — — — — 8,645	8,645
Balance as of January 1, 2018	244 620
(adjusted) 562,119,334 854 455,401 (17,867) (3,774) (222,985) Issuance of shares upon	211,629
completion of registered direct	
offering 60,000,000 78 99,575 — — —	99,653
Issuance of shares upon exercise of	33,033
issuance of singles upon exercise of stock options 5.334.936 7 3.030 — — — —	3,037
Other comprehensive loss before	5,057
reclassifications	
Foreign currency translation	
adjustments — — — 8,260 — —	8,260
Unrealized holding losses on	
available-for-sale debt	
securities, net of tax of \$0 — — — — 1,145 —	1,145
Reclassification from	
accumulated other	
comprehensive income of losses	
on available-for-sale debt	
securities included in net income, net of tax of \$0 — — — — 2,473 —	2,473
Net loss — — — — — — (95,514)	(95,514)
Net 1055  Net 10	16,202
Balance as of December 31, 2018 627,454,270 939 574,208 (9,607) (156) (318,499)	246,885
Issuance of shares upon exercise of	240,003
stock options 3,549,298 4 362 — — —	366
Other comprehensive loss before	300
reclassifications — — — — — — — —	
Foreign currency translation	
adjustments — — — (9,478) — —	(9,478)
Foreign currency gains on	, , ,
intercompany loan of a long-	
term investment nature, net of	
tax of \$0 — — — 11,783 — —	11,783
Unrealized holding losses on	
available-for-sale debt	
securities, net of tax of \$0 — — — 207 —	207
Reclassification from accumulated other	
comprehensive income of losses	
comprehensive income or rosses on available-for-sale debt	
on available for-sale death	
net of tax of \$0 — — — — (13) —	(13)
Net loss — — — — — — — — (13) — — — — — — — — — — — — — — — — — — —	(137,165)
Share-based compensation	(157,100)
expense — — 11,053 — — —	11,053
Balance as of December 31, 2019 631,003,568 \$ 943 \$ 585,623 \$ (7,302) \$ 38 \$ (455,664)	\$ 123,638

# ADAPTIMMUNE THERAPEUTICS PLC CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

	Year ended December 31,			
		2019		2018
Cash flows from operating activities				
Net loss	\$	(137,165)	\$	(95,514)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		7,172		7,188
Amortization		838		622
Share-based compensation expense		11,053		16,202
Realized (gain) loss on available-for-sale debt securities		(13)		2,473
Unrealized foreign exchange losses		1,076		9,747
Other		(185)		237
Changes in operating assets and liabilities:				
Increase in receivables and other operating assets		(1,436)		(5,162)
(Increase) decrease in non-current operating assets		(1,450)		742
Increase (decrease) in payables and deferred revenue		7,603		(40,923)
Net cash used in operating activities		(112,507)		(104,388)
Cash flows from investing activities				
Acquisition of property, plant and equipment		(1,592)		(3,910)
Acquisition of intangibles		(1,482)		(798)
Maturity or redemption of marketable securities		125,303		138,038
Investment in marketable securities		(27,284)		(150,787)
Net cash provided by (used in) investing activities		94,945		(17,457)
Cash flows from financing activities				
Proceeds from issuance of common stock, net of issuance costs of \$0 and \$347		_		99,653
Proceeds from exercise of stock options		366		3,037
Net cash provided by financing activities		366		102,690
		(272)		2 225
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash		(372)		3,335
Net decrease in cash and cash equivalents		(17,568)		(15,820)
Cash, cash equivalents and restricted cash at start of period		72,476		88,296
Cash, cash equivalents and restricted cash at end of period	\$	54,908	\$	72,476
Supplemental cash flow information				
Interest received	\$	3,426	\$	3,114
Income taxes paid	•	201		258

# ADAPTIMMUNE 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 clinical-stage biopharmaceutical company primarily focused on providing novel cell therapies to people with cancer. We are a leader in the development of T-cell therapies for solid tumors. The Company's proprietary SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables it to identify cancer targets, find and genetically engineer T-cell receptors ("TCRs") against those targets, and produce therapeutic candidates ("SPEAR T-cells") for administration to patients.

The Company is subject to a number of risks similar to other biopharmaceutical companies in the early stage of clinical development 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 SPEAR T-cells, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's SPEAR T-cells, the need to develop a reliable commercial manufacturing process, the need to commercialize any T-cell therapies that may be approved for marketing, and protection of proprietary technology. If the Company does not successfully commercialize any of its SPEAR T-cells, it will be unable to generate product revenue or achieve profitability. The Company had an accumulated deficit of \$455.7 million as of December 31, 2019.

#### 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 the valuation of share options, valuation allowances relating to deferred tax assets, revenue recognition, assessment of the utility of clinical materials, estimation of the incremental borrowing rate for operating leases, estimating clinical trial expenses and estimating R&D tax and expenditure credits. 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.

As of December 31, 2019, the Company had cash and cash equivalents of \$50.4 million, marketable securities of \$39.1 million, and stockholders' equity of \$123.6 million. On January 13, 2020, the Company entered into a co-development

and co-commercialization agreement with Astellas Pharma Inc. and received an upfront payment of \$50.0 million in January 2020 under the agreement. The Company is also entitled to receive research funding of up to \$7.5 million per year. On January 24, 2020, the Company closed an underwritten public offering of 21,000,000 American Depository Shares (ADSs) which, together with the full exercise by the underwriters on February 7, 2020 of their option to purchase an additional 3,150,000 ADSs, generated net proceeds of approximately \$89.8 million. These events resolved the conditions previously reported in our Form 10-Q for the three months ended September 30, 2019 that had raised substantial doubt about the Company's ability to continue as a going concern for a period of at least one year from the date the financial statements were issued.

During the year ended December 31, 2019, the Company incurred a net loss of \$137.2 million, used cash of \$112.5 million in its operating activities, and generated revenues of \$1.1 million. The Company has incurred net losses in most periods since inception, and it expects to incur operating losses in future periods.

Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued. Although our financial statements have been prepared on a going concern basis, if the Company fails to obtain additional financing in future, this may raise substantial doubt over the Company's ability to continue as a going concern in future reporting periods.

# (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.

At the end of May 2018, the Company's investments in marketable securities were transferred to the ultimate parent company, Adaptimmune Therapeutics plc, with a U.S. dollar functional currency, which reduced the potential for foreign exchange gains or losses arising on these investments.

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 income (loss).

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 income (loss).

Foreign exchange losses were \$137,000 and \$15,257,000 for the years ended December 31, 2019 and 2018, respectively, and are included within Other income (expense), net in the Consolidated Financial Statements.

# (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

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 income (loss)

The following amounts were reclassified out of other comprehensive income (in thousands):

		Year	t reclassi ended ber 31,	fied	
Component of accumulated other comprehensive income	2019			2018	Affected line item in the Statement of Operations
Unrealized gains (losses) on available- for-sale securities					
Reclassification adjustment for (gains) losses on available-for-sale debt securities	\$ (	(13)	\$	2,473	Other income (expense), 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 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).

	Dec	2019	Dec	2018
Cash and cash equivalents	\$	50,412	\$	68,379
Restricted cash		4,496		4,097
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	\$	54,908	\$	72,476

# (h) Available-for-sale debt securities

As of December 31, 2019, the Company has the following investments in available-for-sale debt securities, which are categorized as cash equivalents or marketable securities – available-for-sale debt securities on the balance sheet depending on their maturity at acquisition (in thousands):

Cash equivalents:	Remaining contractual maturity	Amortized cost	Gross unrealiz gains	ed	Grunrea los	lized	Aggregate estimated fair value
Money market funds	Less than 3 months	\$ 16,822	\$ -		\$	_	\$ 16,822
·		\$ 16,822	\$ -	_	\$	_	\$ 16,822
Marketable securities:							
Corporate debt securities	Less than 3 months	\$ 23,479	\$	7	\$	(1)	\$ 23,485
Corporate debt securities	3 months to 1 year	15,613	3	32		_	15,645
		\$ 39,092	\$ 3	39	\$	(1)	\$ 39,130

As of December 31, 2018, the Company had the following investments in available-for-sale debt securities, which are categorized as cash equivalents or marketable securities — available-for-sale debt securities on the balance sheet depending on their maturity at acquisition (in thousands):

	Maturity	Amortized cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Estimated Fair Value
Marketable securities:					
Corporate debt securities	3 months to 1 year	\$ 102,818	<b>\$</b> 5	\$ (120)	\$ 102,703
Corporate debt securities	1 to 2 years	23,153	_	(43)	23,110
Agency bond	3 months to 1 year	3,963	2	_	3,965
Treasury bills	3 months to 1 year	1,980	_	_	1,980
Certificate of deposit	3 months to 1 year	3,002	_	_	3,002
Commercial paper	3 months to 1 year	1,995	_	_	1,995
		\$ 136,911	\$ 7	\$ (163)	\$ 136,755

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, 2019, the Company has classified all of its available-for-sale debt securities, including those with maturities beyond one year, 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 investment in available-for-sale debt securities is measured at fair value at each reporting date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses, interest income and amortization of premiums and discounts at acquisition are included in other income (expense), net. In the year ended December 31, 2019 and 2018, proceeds from the maturity or redemption of available-for-sale debt securities were \$125,303,000 and \$138,038,000 respectively. There were realized gains (losses) of \$13,000 and \$(2,473,000) recognized on the maturity of available-for-sale debt securities during the year ended December 31, 2019 and 2018, respectively, primarily arising due to foreign exchange movements, and, as a result, the Company reclassified this amount out of accumulated other comprehensive loss for the same period.

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 it is other than temporary. Impairments judged to be other than temporary are included in other income (expense), net when they are identified.

The aggregate fair value (in thousands) and number of securities held by the Company in an unrealized loss position as of December 31, 2019 and 2018 are as follows:

	Dece	De	8		
	Fair market value of	Number of investments	Fair market value of	Number of	
	investments in an	in an unrealized	investments in an	investments in an	
	unrealized loss position	loss Unrealized position losses	unrealized loss position	unrealized loss position	Unrealized losses
Marketable securities:					
Corporate debt securities	\$ 2,013	1 \$ (1)	\$ 117,179	37	\$ (163)

As of December 31, 2019 and 2018, these securities are not considered to be other than temporarily impaired because the impairments are not severe, have been for a short duration and are due to normal market and exchange rate fluctuations. No securities have been in an unrealized loss position for more than one year. Furthermore, the Company does not intend to sell the debt securities in an unrealized loss position, and it is unlikely that the Company will be required to sell these 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 investment in available-for-sale debt securities is 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 are amounts due from customers. As of December 31, 2019 and 2018, the Company had one customer, which was GlaxoSmithKline, or GSK.

Management analyses current and past due accounts and determines if an allowance for uncollectible accounts is required based on collection experience and other relevant information. As of December 31, 2019 and 2018, the allowance for doubtful accounts is \$nil. The process of estimating the uncollectible accounts 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. The Company also assesses whether there is an expected decline in the utility of materials to be purchased under future commitments at the end of each reporting period. Further information is disclosed in Note 9.

# (k) Property, plant and equipment

Property, plant and equipment is stated at cost, less any impairment losses, less accumulated depreciation.

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 are assessed for impairment whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable.

#### (m) Leases prior to the adoption of ASC 842 on January 1, 2019

Costs in respect of operating leases in the year ended December 31, 2018 prior to the adoption of ASC 842 were charged to the Consolidated Statement of Operations on a straight-line basis over the lease term. Rent holidays were recognized on a straight-line basis over the lease term (including any rent holiday period). Lease incentives, including leasehold improvement incentives or allowances, were recorded as deferred rent and amortized as reductions to lease expense over the lease term. Leasehold improvements made by a lessee that were funded by landlord incentives or allowances were recorded as leasehold improvement assets and amortized over the shorter of the useful life of the asset and the non-cancellable lease term.

Lease expenses amounted to \$3,399,000 for the year ended December 31, 2018. These were recorded within research and development and general and administrative expenses in the Company's Consolidated Statements of Operations.

# (n) Leases after the adoption of ASC 842 on January 1, 2019

On January 1, 2019, the Company adopted a new standard, Accounting Standard Update 2016-02 – Leases, which is codified in ASC 842. The comparative financial information for the year ended December 31, 2018 has not been restated and is prepared in accordance with the accounting policies that are described in Note 2 to the Consolidated Financial Statements included in the Annual Report.

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 as they were previously classed as these and the lease classification is not reassessed on adoption of ASC 842. 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. As the Company has no external borrowings, 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 right-of-use 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 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. The term of the lease expires on October 23, 2041, with termination options exercisable by the Company on the fifth anniversary of the lease commencement date and at approximately five yearly intervals thereafter.

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.

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.

The Company has elected not to recognize a right-of-use 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 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.

# (o) 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, 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.

#### (p) Revenue

On January 1, 2018, the Company adopted new guidance on revenue recognition, which has been codified within ASC 606. During the year ended December 31, 2019, the Company had one contract with a customer, which is the GSK Collaboration and License Agreement. The GSK Collaboration and License Agreement consists of multiple performance obligations, including the transition of the NY-ESO SPEAR T-cell program to GSK, the development of a second and third target, and an exclusive license (the "NY-ESO License") to research, develop, and commercialize the Company's NY-ESO SPEAR T-cell therapy program.

In September 2017, GSK exercised its option to obtain the NY-ESO License and a detailed transition plan followed, identifying the steps needed to complete transition of the Investigational New Drug (IND) process with the Food and Drug Administration (FDA) for the NY-ESO SPEAR T-cell program to GSK. On July 23, 2018, the transition activities were substantially completed and the IND for the NY-ESO SPEAR T-cell program transferred to GSK.

GSK nominated a second target program for the PRAME target antigen, which was announced on 9 January 2017. The Company completed all work under this collaboration program in 2018. The program led to the development of a final lead candidate SPEAR T-cell directed to a specific peptide from the PRAME antigen. GSK and Adaptimmune agreed that the collaboration should not continue due to the peptide, to which the lead candidate was directed, not reaching GSK criteria.

In 2019, GSK has nominated its third target under the Collaboration and License Agreement. Development of products to this target commenced in the year ended December 31, 2019, and the Company received \$3.2 million following the nomination of the target. The development of products to the third target is a separate performance obligation. Revenue allocated to this performance obligation is expected to be recognized by the end of 2020 as the development progresses. Future revenues will depend on the progress of the development programs within the Collaboration and License Agreement, and GSK's progress with the NY-ESO program, which are difficult to predict.

There was no variable consideration at December 31, 2019. 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.

Under the terms of the GSK Collaboration and License Agreement, the Company may also be entitled to development milestones. The development and regulatory milestones are per product milestones and are dependent on achievement of certain obligations, the nature of the product being developed, stage of development of product, territory in which an obligation is achieved and type of indication or indications in relation to which the product is being developed. In addition, for any program multiple products may be developed to address different HLA-types. These amounts have not been included within the transaction price as of December 31, 2019 because they are not considered probable.

The Company may also receive commercialization milestones upon the first commercial sale of a product based on the indication and the territory and mid-single to low double-digit royalties on worldwide net sales. These amounts have not been included within the transaction price as of December 31, 2019 because they are sales or usage-based royalties promised in exchange for a license of intellectual property, which will be recognized when the subsequent sale or usage occurs.

The payments to the Company under the contract are typically due upon achievement of milestones and within standard payment terms (approximating to 45 days). The contract does not include a significant financing component.

The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligations. The Company satisfies the performance obligations relating to the development of each target over time and recognizes 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 considers that this depicts the progress of the project, where the significant inputs are internal project resource and third-party clinical and manufacturing costs. The determination of the percentage of completion requires the Company to estimate the costs-to-complete the project. The Company makes a detailed estimate of the costs-to-complete on an annual basis as part of the Company's budgeting process, 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 is adjusted and the revenue is 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 is recognized as an adjustment to revenue in the period in which the change in estimate occurs.

The previous performance obligation relating to the NY-ESO License was recognized at a point-in-time, upon commencement of the license in 2018.

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 to 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.

Revenue is recognized when earned and realized or realizable, which is generally when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller's price to the buyer is fixed or determinable, and collectability is reasonably assured. Where applicable, all revenues are stated net of value added and similar taxes.

# (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 expensed acquired in-process R&D of \$4,556,000, and \$210,000 in the years ended December 31, 2019 and 2018, respectively.

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. Reimbursable R&D tax and expenditure credits were \$18,649,000 and \$17,299,000 in the years ended December 31, 2019 and 2018, respectively.

# (r) Share-based compensation

The Company awards certain employees and non-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, 2019 and 2018 were \$1,904,000 and \$1,847,000, respectively.

# (t) 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.

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 when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company evaluates the realizability of its deferred tax assets by assessing its valuation allowance and by adjusting the amount of such 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 unrecognized tax benefits within the Consolidated Statement of Operations as income tax expense.

In interim periods, the income tax expense (benefit) related to income (loss) from continuing operations before income tax expense (benefit) excluding significant unusual or infrequently occurring items is computed at an estimated annual effective tax rate and the income tax expense (benefit) related to all other items is individually computed and recognized when the items occur.

#### (u) 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.

The following table reconciles the numerator and denominator in the basic and diluted loss per share computation (in thousands):

	Year ended			
	December 31,			
	2019 2018			
Numerator for basic and diluted loss per share				
Net loss	\$	(137,165)	\$	(95,514)
Net loss attributable to shareholders used for basic and diluted EPS calculation	\$	(137,165)	\$	(95,514)
Denominator for basic and diluted loss per share				
Weighted average number of shares used to calculate basic and diluted loss per share	6	29,805,218	58	34,338,942

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 e	naea	
	December 31,		
	2019 2018		
Weighted average number of share options	96,675,101	88,553,474	

From January 1, 2020 through to February 29, 2020, the Company granted 10,229,280 options over ordinary shares with an exercise price determined by reference to the market value of an ADS at the date of grant, and 6,060,696 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.

# (v) New accounting pronouncements

Adopted in the year ended December 31, 2019

#### **Leases**

On January 1, 2019, the Company adopted Accounting Standard Update 2016-02 – Leases, which is codified in ASC 842. The Company has adopted the guidance using the modified retrospective approach, with the cumulative effect of initially applying the guidance recognized as an adjustment to the opening balance of equity at January 1, 2019. Therefore, the comparative information has not been adjusted and continues to be reported under previous guidance. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed it to carry forward the historical lease classification of the Company's leases as operating leases. The effect on the accumulated deficit, total stockholders' equity and net assets as at January 1, 2019 was \$0.

The adoption of ASC 842 has had a material impact on the Company's financial statements. At January 1, 2019 the Company recognized right-of-use assets and liabilities for operating leases following the adoption date of \$22.2 million and \$26.9 million respectively and derecognized \$4.7 million of other liabilities and prepayments that had been recognized under previous guidance.

To be adopted in future periods

#### Measurement of Credit Losses on Financial Instruments

In June 2016, the FASB issued ASU 2016-13 - Financial Instruments - Credit losses, which replaces the incurred loss impairment methodology for financial instruments in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The guidance is effective for the fiscal year beginning January 1, 2020, including interim periods within that fiscal year. The FASB has issued ASU 2019-10 which has resulted in the postponement of the effective date of the new guidance for eligible smaller reporting companies to the fiscal year beginning January 1, 2023. The Company currently intends to adopt the guidance in the fiscal year beginning January 1, 2023. The guidance must be adopted using a modified-retrospective approach and a prospective transition approach is required for debt securities for which an other-than-temporary impairment had been recognized before the effective date. The Company is currently evaluating the impact of the guidance on its Consolidated Financial Statements.

#### Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract

In August 2018, the FASB issued ASU 2018-15 – Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40) Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The guidance is effective for the fiscal year beginning January 1, 2020, including interim periods within that fiscal year. The guidance may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company does not expect the impact of the guidance to have a material impact on the Consolidated Financial Statements.

# Changes to the Disclosure Requirements for Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13 — Fair Value Measurement (Topic 820) - Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The guidance is effective for the fiscal year beginning January 1, 2020, including interim periods within that fiscal year. Certain amendments apply prospectively with the all other amendments applied retrospectively to all periods presented upon their effective date. The Company does not expect the impact of the guidance to have a material impact on the Consolidated Financial Statements.

#### Revenue Recognition in Collaborative Arrangements

In November 2018, the FASB issued ASU 2018-18 – Collaborative Arrangements — Clarifying the Interaction between Topic 808 and Topic 606, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The Company will adopt the guidance from Jan 1, 2020 and is still assessing the impact on its collaboration deals but does not expect it to be material.

#### Note 3 — Revenue

Revenue from contracts with customers arises from one customer, which is GSK, in one geographic location, which is the United Kingdom.

Revenue comprises the following categories (in thousands):

	Year ended December 31,			
	2019	2018		
Development	\$ 1,122	\$	20,391	
Licenses	_		39,114	
	\$ 1,122	\$	59,505	

The deferred revenue balance as of January 1, 2019 and 2018 respectively, and December 31, 2019 and 2018 respectively is as follows (in thousands):

		2018	
Deferred revenue at January 1	\$		\$ 30,090
Amounts invoiced in the period		3,217	30,077
Revenue in the period		(1,122)	(59,505)
Changes in variable consideration		_	(10,396)
Changes in the measure of progress		_	5,027
Foreign exchange arising on consolidation		33	4,707
Deferred revenue at December 31	\$	2,128	\$ _

The amount of the transaction price received that is allocated to performance obligations that are unsatisfied or partially satisfied at December 31, 2019 was \$2.1 million. The revenue allocated to the third target program will be recognized over an estimated period up to the end of 2020 as the development of products to the target progresses.

# **Note 4** — Financial instruments

The Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, restricted cash, accounts receivable, accounts payable and accrued expenses.

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, 2019 are as follows (in thousands):

			Fair value measurements usin				ng
	December 31, 2019		Level 1	Level 2		Le	vel 3
Assets:							
Marketable securities:							
Corporate debt securities	\$	39,130	\$ 39,130	\$	_	\$	_
	\$	39,130	\$ 39,130	\$	_	\$	_

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, 2018 are as follows (in thousands):

		Fair val	nts using		
	December 31,	Level 1	Level 1 Level 2		
	2018				
Assets:					
Marketable securities:					
Corporate debt securities	\$ 125,813	\$ 125,813	\$ —	\$ —	
Agency bond	3,965	_	3,965	_	
Treasury bills	1,980	_	1,980	_	
Certificate of deposit	3,002	_	3,002	_	
Commercial paper	1,995	_	1,995	_	
	\$ 136,755	\$ 125,813	\$ 10,942	\$ —	

The Company estimates the fair value of available-for-sale debt securities 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 \$50,412,000, marketable securities of \$39,130,000 and restricted cash of \$4,496,000 as of December 31, 2019. 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 has one customer as a result of the GSK Collaboration and License Agreement. There were no trade receivables as of December 31, 2019 and \$192,000 as of December 31, 2018. Trade receivables arise in relation to the GSK Collaboration and License Agreement. The Company has been transacting with GSK since June 2014, during which time no impairment losses have been recognized. As of December 31, 2019, there were no overdue accounts receivable.

# Foreign exchange risk

The Company is exposed to foreign exchange rate risk because it operates in the United Kingdom and the United States. The Company's revenue from the GSK Collaboration and License Agreement is denominated in pounds sterling and is generated by our U.K.-based subsidiary, which has a pounds sterling functional currency. As a result, these sales are subject to translation into U.S. Dollars when the financial statements are consolidated. Expenses are generally denominated in the currency in which the Company's operations are located, 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, Furos

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, 2019, the last business day of the reporting period, was £1.00 to \$1.31.

# 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. 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):

	Dec	December 31, 2019		ember 31, 2018
Corporate tax receivable	\$	19,284	\$	16,459
Prepayments		8,395		6,279
Clinical materials		1,459		1,087
VAT receivable		1,387		1,505
Other current assets		422		439
	\$	30,947	\$	25,769

# Note 6 — Property, plant and equipment, net

Property and equipment, net consisted of the following (in thousands):

	De	December 31, 2019		cember 31, 2018
Computer equipment	\$	3,069	\$	2,916
Laboratory equipment		23,464		21,280
Office equipment		864		847
Leasehold improvements		27,320		26,873
Assets under construction				126
		54,717		52,042
Less accumulated depreciation		(23,649)		(15,924)
	\$	31,068	\$	36,118

Depreciation expense was \$7,172,000 and \$7,188,000 for the years ended December 31, 2019 and 2018, respectively.

# Note 7 — Intangible assets, net

Intangible assets, net consisted of the following (in thousands):

	December 31,		Dec	ember 31,
		2019		2018
Third party software licenses and development	\$	4,095	\$	2,494
Licensed IP rights – completed technology used in R&D		204		197
		4,299		2,691
Less accumulated amortization		(2,101)		(1,218)
	\$	2,198	\$	1,473

Amortization expense was \$838,000 and \$622,000 for the years ended December 31, 2019 and 2018, respectively. The estimated aggregate amortization expense in respect of these assets for each of the five years ended 2024 is \$887,000, \$668,000, \$535,000, \$102,000 and \$-, respectively.

# Note 8 — Operating leases

The following table shows the lease costs for the year ended December 31, 2019 (in thousands):

		Year ended
		December 31,
	_	2019
Lease cost:		
Operating lease cost	\$	4,017
Short-term lease cost		319
	\$	4,336
	<del></del>	
		Year ended
		December 31,
		2019
Other information:		
Operating cash flows from operating leases (in thousands)	\$	4,063
		December 31,
		2019
	·	
Weighted-average remaining lease term - operating leases		7.3 years
Weighted-average discount rate - operating leases		7.2%

The maturities of operating lease liabilities as of December 31, 2019 are as follows (in thousands):

	Oper	ating leases
2020	\$	4,191
2021		4,234
2022		4,237
2023		4,004
2024		3,936
after 2024		12,748
Total lease payments		33,350
Less: Imputed interest		(7,890)
Present value of lease liability	\$	25,460

The Company has operating leases in relation to property for office and research facilities. The maximum lease term without activation of termination options is to 2041.

# Note 9 — Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	Dec	cember 31, 2019	December 31, 2018		
Accrued clinical and development expenditure	\$	8,782	\$	9,637	
Accrued employee expenses		6,863		7,553	
Other accrued expenditure		2,662		2,422	
Accrued purchase commitments		5,000		_	
Other		56		742	
	\$	23,363	\$	20,354	

In 2016, the Company entered into a supply agreement with ThermoFisher for the supply of the Dynabeads® CD3/CD28 technology. The supply agreement runs until December 31, 2025. Under the supply agreement, the Company is required to purchase its requirements for CD3/CD28 magnetic bead product exclusively from ThermoFisher for a period of 5 years. There are minimum purchasing obligations of \$5.0 million, \$2.5 million of which is payable in 2020 and \$2.5 million of which is payable in 2021. Management regularly updates the assessment of the utility of the Dynabeads, and in the year ended December 31, 2019, considered that there is sufficient uncertainty surrounding the utility of the Dynabeads, which is dependent upon current study trajectories, the Company's clinical pipeline, manufacturing methods and undetermined future projects, to result in the \$5.0 million purchase commitment being recognized in Research and development expense in the year ended December 31, 2019.

#### Note 10 — Contingencies and commitments

#### Leases

Lease payments under operating leases as of December 31, 2019 and information about the Company's lease arrangements are disclosed in Note 8.

Future minimum lease payments under non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2018 were (in thousands):

	0	perating leases
2019	\$	3,682
2020		3,695
2021		3,728
2022		3,772
2023		3,309
Thereafter		13,772
	\$	31,958

# Capital commitments

As of December 31, 2019, the Company had commitments for capital expenditure totaling \$414,000, which the Company expects to incur within one year.

Commitments for clinical materials, clinical trials and contract manufacturina

As of December 31, 2019, the Company had non-cancellable commitments for purchase of clinical materials, contract manufacturing, maintenance, and committed funding under the MD Anderson strategic alliance of up to \$13,657,000, of which the Company expects to pay \$6,552,000 within one year and \$7,105,000 in one to three 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 \$32,788,000 and \$41,580,000 for the years ended December 31, 2019 and 2018, respectively.

In addition to the above commitments, the company has recognized commitments for the purchase of clinical materials of \$5,000,000 in the year ended December 31, 2019, \$2,500,000 of which the Company expects to pay within one year, and \$2,500,000 of which the Company expects to pay in one to three years. Further details of these commitments are provided in Note 9.

Bellicum Pharmaceuticals Inc., Co-Development and Co-Commercialization Agreement

On December 16, 2016, the Company entered into a Co-Development and Co-Commercialization Agreement with Bellicum Pharmaceuticals, Inc. ("Bellicum") in order to facilitate a staged collaboration to evaluate, develop and commercialize next generation T-cell therapies.

Under the agreement, the Company will evaluate Bellicum's GoTCR technology (inducible MyD88/CD40 costimulation, or iMC) with the Company's SPEAR T-cells for the potential to create enhanced T-cell therapeutics. Depending on results of the initial preclinical proof-of-concept phase, the agreement may progress to a two-target co-development and co-commercialization phase. To the extent necessary, and in furtherance of the parties' proof-of-concept and co-development efforts, the parties granted each other a royalty-free, non-transferable, non-exclusive license covering their respective technologies for purposes of facilitating such proof-of-concept and co-development efforts. In addition, as to covered therapies developed under the agreement, the parties granted each other a reciprocal exclusive license for the commercialization of such therapies. During the proof of concept phase, each party bears its own costs and there are no payments made between the Company and Bellicum. Any research and development costs incurred by the Company with third parties have been accounted for in accordance with the Company's accounting policy for research and development expenses.

With respect to any joint commercialization of a covered therapy, the parties agreed to negotiate in good faith the commercially reasonable terms of a co-commercialization agreement. The parties also agreed that any such agreement shall provide for, among other things, equal sharing of the costs of any such joint commercialization and the calculation of profit shares as set forth in the agreement.

The agreement will expire on a country-by-country basis once the parties cease commercialization of the T-cell therapies covered by the agreement, unless earlier terminated by either party for material breach, non-performance or cessation of development, bankruptcy/insolvency, or failure to progress to co-development phase.

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 are collaborating on a number of studies including clinical and preclinical development of the Company's SPEAR T-cell therapies targeting NY-ESO, MAGE-A10 and MAGE-A4 and will collaborate on future clinical stage first and second generation SPEAR T-cell therapies across a number of cancers.

Under the terms of the agreement, the Company committed at least \$19,644,000 to fund studies. Payment of this funding is contingent on mutual agreement to study orders in order for any study to be included under the alliance

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 milestone payments of \$2,325,000 in the year ended December 31, 2018. The Company is obligated to make further payments to MD Anderson as certain milestones are achieved. These costs are expensed to research and development as MD Anderson renders the services under the strategic alliance.

The agreement may be terminated by either party for material breach by the other party. Individual studies may be terminated for, amongst other things, material breach, health and safety concerns or where the institutional review board, the review board at the clinical site with oversight of the clinical study, requests termination of any study. Where any legal or regulatory authorization is finally withdrawn or terminated, the relevant study will also terminate automatically.

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 Company paid an upfront license and start-up fee of \$2.5 million to Universal Cells in November 2015, a milestone payment of \$3.0 million in February 2016 and further milestone payments of \$0.2 million and \$0.9 million were made in the year ended December 31, 2018 and 2017, respectively. The agreement was amended and re-stated as at January 13, 2020, primarily to reflect changes to the development plan agreed between the parties. Further milestone payments of up to \$38.4 million are payable if certain development and product milestones are achieved. Universal Cells would also receive a profit-share payment for the first product, and royalties on sales of other products utilizing its technology. The upfront license and start-up fee and milestone payments were expensed to research and development when incurred.

#### Noile-Immune Collaboration Agreement

On August 26, 2019, the Company entered into a collaboration and license agreement relating to the development of next-generation SPEAR T-cell products with Noile-Immune Biotech Inc. ("Noile-Immune"). 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 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 SPEAR T-cell products with Alpine Immune Sciences Inc. ("Alpine"). The Company 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 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. 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 provide the Company with a field-based exclusive license under certain intellectual property rights owned or controlled by ThermoFisher. The Company paid upfront license fees of \$1.0 million relating to the license and sublicense agreements and has an obligation to pay minimum annual royalties (in the tens of thousands of U.S. dollars prior to licensed product approval and thereafter at a level of 50% of running royalties in the previous year), milestone payments and a low single-digit running royalty payable on the net selling price of each licensed product. The upfront payment made in 2012 was expensed to research and development when incurred. Subsequent milestone payments have been recognized as an intangible asset due to the

technology having alternative future use in research and development projects at the time of the payment. The minimum annual royalties have been expensed as incurred.

In 2016, the Company entered into a supply agreement with ThermoFisher for the supply of the Dynabeads® CD3/CD28 technology. The Dynabeads® CD3/CD28 technology is designed to isolate, activate and expand human T-cells, and is being used in the manufacturing of the Company's affinity enhanced T-cell therapies. The supply agreement runs until December 31, 2025. Under the supply agreement the Company is required to purchase its requirements for CD3/CD28 magnetic bead product from ThermoFisher for a period of 5 years and there are also minimum purchasing obligations. \$5.0 million of these purchase commitments have been recognized in research and development expense in the year ended December 31, 2019. \$2.5 million of the purchase commitments are payable in 2020 and \$2.5 million are payable in 2021. ThermoFisher has the right to terminate the supply agreement for material breach or insolvency.

# Note 11 — Stockholders' equity

#### Ordinary shares

Each holder of ordinary shares is entitled to one vote, on a show of hands and one vote per share on a poll, at general meetings of the Company. On the winding up of the Company, the assets of the Company available for distribution to holders remaining after payment of all other debts and liabilities of the Company shall be paid to the shareholders in proportion to the number of shares held by each of them. The payment of dividends by Adaptimmune Therapeutics plc is governed by English law. As of December 31, 2019, Adaptimmune Therapeutics Plc and Adaptimmune Limited have accumulated net losses.

Effective from May 2, 2019, the Directors have the authority to allot new ordinary shares or to grant rights to subscribe for or to convert any security into ordinary shares in the Company up to a maximum aggregate nominal amount of £207,288.00. This authority runs for five years and will expire on May 1, 2024 (unless previously renewed, varied or revoked). Effective from May 2, 2019, the Directors also have the authority to allot ordinary shares for cash or to grant rights to subscribe for or to convert any security into ordinary shares in the Company without first offering them to existing shareholders in proportion to their existing holdings up to an aggregate maximum nominal amount of £157,500.00. This power will expire at the end of the Annual General Meeting of the Company to be held in 2021 (unless previously renewed, varied or revoked).

#### 2020 Underwritten public offering

Details of the Company's public offering subsequent to December 31, 2019 are provided in Note 15.

# 2018 Registered direct offering

On September 7, 2018, the Company completed a registered direct offering of its American Depositary Shares ("ADSs") following its entry into a definitive agreement with Matrix Capital Management Company, LP, New Enterprise Associates 16, L.P., New Enterprise Associates 14, L.P. and Syncona Portfolio Limited. The Company sold 10,000,000 ADSs (representing 60,000,000 ordinary shares) at a price of \$10.00 per ADS. The net proceeds were \$99,653,000 after deducting offering expenses of \$347,000.

# Note 12 — Share-based compensation

The Company grants 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 £30,000 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, 2019 are 25% on the first anniversary of the grant date and 75% in monthly installments over the following three years. However, the options 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,	25% on the first anniversary of the grant date and 75% in
2016:	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,	25% on the first anniversary of the grant date and 75% in
2016:	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

Effective from January 2018, the Company has also granted restricted stock unit style options ("RSU-style"). The RSU-style options over ordinary shares in Adaptimmune Therapeutics plc are 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  $\mathfrak{L}0.001$ , 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 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.

Generally, the vesting dates for the Replacement Options under the Adaptimmune Limited schemes are:

Options granted in 2009:	100% on the third anniversary of the grant date
Options granted in 2011, 2012,	25% on the first anniversary of the grant date and 75% in annual
2013 and April 2014:	installments over the following three years
Options granted in	25% on the first anniversary of the grant date and 75% in monthly
December 2014:	installments over the following three years

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 Statement of Operations (thousands):

	Year ended December 31,			
	 2019	2018		
Research and development	\$ 3,812	\$	8,340	
General and administrative	7,241		7,862	
	\$ 11,053	\$	16,202	

As of December 31, 2019, there was \$10,030,000 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 2.6 years.

The following table shows information about share options granted:

	Year ended			
	 December 31,			
	 2019 2018			
Number of options over ordinary shares granted	15,679,383		20,771,970	
Weighted average fair value of ordinary shares options	\$ 0.48	\$	0.87	
Number of RSU-style options granted	8,020,410		8,603,676	
Weighted average fair value of RSU-style options granted	\$ 0.86	\$	1.37	

The following table summarizes all stock option activity for the year ended December 31, 2019:

	Options	exe	Veighted overage orcise price or option	Average remaining contractual term (years)	intrii	gregate isic value ousands)
Outstanding at January 1, 2019	87,564,719	£	0.60			
Changes during the period:						
Granted	23,699,793	£	0.41			
Exercised	(3,549,298)	£	0.08			
Forfeited	(18,837,142)	£	0.60			
Outstanding at December 31, 2019	88,878,072	£	0.57	6.8	£	1,991
Exercisable at December 31, 2019	51,953,196	£	0.63	5.6	£	263

The following table summarizes information about stock options granted based on the market value at grant date which were outstanding as of December 31, 2019:

	Options	exer	eighted verage cise price r option	Average remaining contractual term (years)	Aggregate intrinsic value (thousands)
Outstanding at January 1, 2019	79,465,357	£	0.66		
Changes during the period:					
Granted	15,679,383	£	0.62		
Exercised	(2,406,298)	£	0.12		
Forfeited	(16,092,106)	£	0.70		
Outstanding at December 31, 2019	76,646,336	£	0.66	6.5	£ 139
Exercisable at December 31, 2019	51,137,121	£	0.64	5.6	£ 139

The following table summarizes information about options which have a nominal exercise price (similar to restricted stock units (RSUs)) which were outstanding as of December 31, 2019:

	Options	Average remaining contractual term (years)	Aggregate intrinsic value (thousands)
Outstanding at January 1, 2019	8,099,362		
Changes during the period:			
Granted	8,020,410		
Exercised	(1,143,000)		
Forfeited	(2,745,036)		
Outstanding at December 31, 2019	12,231,736	8.7	£ 1,851
Exercisable at December 31, 2019	816,075	8.0	£ 124

There were 3,549,298 and 5,334,936 share options exercised in the years ended December 31, 2019 and 2018, respectively. In the years ended December 31, 2019 and 2018 the total intrinsic value of stock options exercised was \$1,977,000 and \$6,727,000, respectively and the cash received from exercise of stock options was \$366,000 and \$3,037,000, 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 \$1,488,000 and \$1,325,000 and for the years ended December 31, 2019 and 2018, respectively. The Company satisfies the exercise of stock options through newly issued shares.

	Outstanding					Exercisable			
Exe	ercise price	Total share options	Weighted- average remaining contractual life		Weighted- average exercise price	Total share options		Weighted- average exercise price	
£	0	12,231,786	8.7	£	0.00	816,075	£	_	
	0.01 - 0.25	5,751,306	3.1		0.14	4,920,306		0.12	
	0.26 - 0.50	15,451,247	5.4		0.42	12,908,168		0.41	
	0.51 - 0.75	33,649,220	7.5		0.63	16,744,149		0.61	
	0.76 - 1.00	17,894,778	6.5		0.93	13,651,919		0.92	
	1.01 - 1.50	2,283,984	7.5		1.19	1,448,622		1.13	
	1.51 - 2.00	1,615,801	7.8		1.70	1,463,957		1.70	
To	tal	88,878,122	6.8	£	0.57	51,953,196	£	0.63	

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 e	nded
	Decemb	er 31,
	2019	2018
Expected term (years)	5 years	5 years
Expected volatility	69 - 73%	66 - 69%
Risk free rate	0.22 - 0.90%	0.90 - 1.15%
Expected dividend yield	0%	0%

The expected term of the option is based on management judgment. 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 taxes is as follows (in thousands):

	I	Year ended December 31,			
	2019	2019 2018			
United States	\$ (4	<del>194)</del> \$	(1,650)		
United Kingdom	(136,4	29)	(93,367)		
Loss before income taxes	\$ (136,9	(23)	(95,017)		

The components of income tax expense are as follows (in thousands):

	Year ended December 31,		
	2019	2018	
United States:			
Federal	\$ 242	\$	400
State and local	_		97
United Kingdom	_		_
Total current tax expense	242		497
United States:			
Federal	_		_
State and local	_		_
United Kingdom	_		_
Total deferred tax expense			_
Total income tax expense	\$ 242	\$	497

As of December 31, 2019 and 2018 the tax effects of temporary differences and carryforwards that give rise to deferred tax assets and liabilities were as follows (in thousands):

	Dec	December 31, 2019		December 31, 2018	
Deferred tax liabilities					
Property, plant and equipment	\$	(1,251)	\$	(1,415)	
Right-of-use assets		(2,364)		—	
Other		(79)			
Total		(3,694)		(1,415)	
Deferred tax assets					
Share-based compensation expense		9,941		8,020	
Intangibles		1,413		575	
Operating lease liabilities		2,550		_	
Net operating loss and expenditure credit carryforwards		48,837		33,310	
Other		125		286	
Total		62,866		42,191	
Valuation allowance		(59,172)		(40,776)	
		3,694		1,415	
Net deferred tax asset (liability)	\$	_	\$		

The valuation allowances are primarily related to deferred tax assets for operating loss and tax credit carry-forwards and temporary differences relating to share-based compensation expense. 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.

The movements in the deferred tax valuation allowance for the year ended December 31, 2019 and 2018 is as follows (thousands):

	2019	2018
Valuation allowance at January 1	\$ 40,776	\$ 27,433
Impact of adopting ASC 606		(1,469)
Valuation allowance at January 1, restated	40,776	25,964
Increase in valuation allowance	16,961	16,659
Foreign currency translation adjustments	 1,435	 (1,847)
Valuation allowance at December 31	\$ 59,172	\$ 40,776

Reconciliation of the U.K. statutory income tax rate to the Company's effective tax rate is as follows (in percentages):

	Year ended December 31,		
	2019	2018	
U.K. tax rate	19.0 %	19.0 %	
Reimbursable tax credits within Research and development expense	2.8 %	3.5 %	
R&D expenditures surrendered for R&D tax credit refund	(7.7)%	(10.0)%	
Permanent differences for unrealized foreign exchange on intercompany loans of a long-			
term investment nature	(1.5)%	— %	
Change in valuation allowances	(12.4)%	(17.5)%	
Difference in tax rates	(1.2)%	(1.3)%	
R&D tax credits generated	1.5 %	5.1 %	
Other	(0.7)%	0.8 %	
Effective income tax rate	(0.2)%	(0.5)%	

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 weighted-average U.K. corporate tax rate for the years ended December 31, 2019 and 2018 was 19% in both years. The Company's subsidiary in the United States has generated taxable profits due to a service agreement between the Company's subsidiaries in the United States and the United Kingdom. The U.S. federal corporate tax rate was 21% for the years ended December 31, 2019 and 2018, respectively.

The United Kingdom's 2016 Finance Bill, which was enacted on September 15, 2016, contained reductions in corporation tax to 19% from April 1, 2017 and 17% from April 1, 2020. The Company used a 17% tax rate as of December 31, 2019 in respect of the measurement of deferred taxes arising in the United Kingdom, which reflects the currently enacted tax rate and the anticipated timing of the unwinding of the deferred tax balances. In respect of the measurement of deferred taxes arising in the U.S, the Company has adopted a 21% tax rate as of December 31, 2019.

As of December 31, 2019, we do not have unremitted earnings in our U.S. subsidiary.

As of December 31, 2019, we had U.K. net operating losses of approximately \$249.8 million, expenditure credit carryforwards of \$0.7 million and U.S. tax credit carryforwards of \$5.7 million. Unsurrendered U.K. tax losses and tax credit carryforwards can be carried forward indefinitely to be offset against future taxable profits, however this is restricted to an annual £5 million 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.S. tax credit carryforwards can be carried forward for 20 years. The tax credit carryforwards expire between 2036 and 2039.

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 2012 and prior in the United Kingdom. However, U.K. net operating losses from the tax years 2012 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 Her Majesty's Revenue and Customs through the period ended December 31, 2016. The Company is subject to examinations by tax authorities in the United States for all tax years 2013 through 2019. Our U.S. federal income tax return for the year ended June 30, 2014 was audited by the U.S. Internal Revenue Service and resulted in no changes and our U.S. federal income tax return for the year ended December 31, 2016 is being audited by the U.S. Internal Revenue Service. 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 the uncertainties described above. As of December 31, 2019 and December 31, 2018, the Company had no unrecognized tax benefits.

#### Note 14 — Geographic information

Operations by geographic area

Revenue represents recognized income from the GSK Collaboration and License Agreement. All revenue was derived in the United Kingdom.

Long-lived assets (excluding intangibles and financial instruments) were located as follows (in thousands):

	De	December 31, 2019		December 31, 2018	
United Kingdom	\$	27,367	\$	18,828	
United States		24,490		17,290	
Total long-lived assets <sup>(1)</sup>	\$	51,857	\$	36,118	

- (1) Clinical materials of \$2,503,000 and \$3,953,000, included within non-current assets as of December 31, 2019 and 2018, respectively, are not included within the table above because they can easily be transferred between geographic locations.
- (2) Operating lease right-of-use assets have been included within the above figures for the year ended December 31, 2019 following the transition to ASC 842.

Major customers:

During the years ended December 31, 2019 and 2018, 100% of revenues were generated from one customer, which was GSK.

# Note 15 — Subsequent events

On January 13, 2020, the Company entered into a co-development and co-commercialization agreement with Astellas Pharma, Inc. (the "Astellas Collaboration Agreement"). The Company received an upfront payment of \$50.0 million in January 2020 under the agreement and will receive research funding of up to \$7.5 million per year from the start of research programs under the agreement. Additional milestones are possible under the agreement, but these are dependent on the success of the development and commercialization of research and products.

On January 24, 2020, the Company closed an underwritten public offering of 21,000,000 American Depository Shares (ADSs) which, together with the full exercise by the underwriters on February 7, 2020 of their option to purchase an additional 3,150,000 ADSs, generated net proceeds of approximately \$89.8 million.

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

The following is a description of the ordinary shares, par value £0.001 per share, of Adaptimmune Therapeutics plc (the "Company," "we" or "us") which are represented by American Depositary Shares ("ADSs") with each ADS representing six of our ordinary shares registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This description also summarizes relevant provisions of English law. The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of English law and the Company's articles of association, a copy of which is filed as Exhibit 3.1 to the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2019 (the "2019 Annual Report"). We encourage you to read the articles and the applicable provisions of English law for additional information.

#### **DESCRIPTION OF ORDINARY SHARES**

#### General

As of February 26, 2020 the number of outstanding ordinary shares, par value £0.001 per share, of the Registrant is 780,451,790. There are currently no preferred shares outstanding. All ordinary shares have the same rights and rank *pari passu* in all respects. Subject to the provisions of the Companies Act 2006 and any other relevant legislation, our shares may be issued with such preferred, deferred or other rights, or such restrictions, whether in relation to dividends, returns of capital, voting or otherwise, as we may determine by ordinary resolution (or, failing any such determination, as the directors may determine).

#### **Ordinary Shares**

#### **Voting Rights**

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 corporation, has one vote. On a show of hands, each proxy present in person who has been duly appointed by one or more shareholders 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.

#### Restrictions on Voting Where Sums Overdue on Shares

None of our shareholders (whether present in person by proxy or, in the case of a corporate member, by a duly authorized representative) shall (unless the directors otherwise determine) be entitled to vote at any general meeting or at any separate class meeting in respect of any share held by him unless all calls or other sums payable by him in respect of that share have been paid.

### Calls on Shares

The directors may from time to time make calls on shareholders in respect of any moneys unpaid on their shares, whether in respect of the nominal value of the shares or by way of premium. Shareholders are required to pay called amounts on shares subject to receiving at least 14 clear days' notice specifying the time and place for payment. If a shareholder fails to pay any part of a call, the directors may serve further notice naming another day not being less than 14 clear days from the date of the further notice requiring payment and stating that in the event of non-payment the shares in respect of which the call was made will be liable to be forfeited. Subsequent forfeiture requires a resolution by the directors.

#### **Dividend Rights**

Subject to the Companies Act 2006 and the provisions of all other relevant legislation, we may by ordinary resolution declare dividends 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 pay fixed dividends payable on any of our shares with preferential rights, half-yearly or otherwise, on fixed dates and 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). We may, upon the recommendation of the directors, by ordinary resolution, direct payment of a dividend wholly or partly by the distribution of specific assets.

#### Distributions of Assets on Winding-up

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.

On any winding-up of the Company (whether the liquidation is voluntary, under supervision or by the Court, the liquidator may with the authority of a special resolution of the Company and any other sanction required by any relevant legislation, divide among our shareholders (excluding the Company itself to the extent that it is a shareholder by virtue of its holding any shares or treasury shares) in specie or in kind the whole or any part of our assets (subject to any special rights attached to any shares issued by us in the future) and may for that purpose set such value as he deems fair upon any one or more class or classes of property and may determine how that division shall be carried out as between the shareholders or different classes of shareholders. The liquidator may, with that sanction, vest the whole or any part of the assets in trustees upon such trusts for the benefit of the shareholders as he with the relevant authority determines, and the liquidation of the Company may be closed and the Company dissolved, but so that no shareholders shall be compelled to accept any shares or other property in respect of which there is a liability.

#### Variation of Rights

The rights or privileges attached to any class of shares may (unless otherwise provided by the terms of the issue of the shares of that class) be varied or abrogated with the consent in writing of the holders of three-fourths in requisite amount of the issued shares of that class (excluding any shares of that class held as treasury shares) or with the sanction of a special resolution passed at a separate general meeting of the shareholders of that class, but not otherwise.

#### **Transfer of Shares**

All of our shares are in registered form and may be transferred by a transfer in any usual or common form or any form acceptable to the directors and permitted by the Companies Act 2006 and any other relevant legislation.

#### **Capital Variations**

We may, by ordinary resolution, consolidate and divide all or any of our share capital into shares of a larger nominal amount than our existing shares or sub-divide our shares, or any of them, into shares of a smaller amount than our existing shares. Subject to the provisions of the Companies Act 2006 and any other relevant legislation, we may by special resolution reduce our share capital, any capital redemption reserve fund or any share premium account and may redeem or purchase any of our own shares.

# **Pre-emption Rights**

There are no rights of pre-emption under our articles of association in respect of transfers of issued ordinary shares. In certain circumstances, our shareholders may have statutory pre-emption rights under the Companies Act 2006 in respect of the allotment of new shares in the Company. These statutory pre-emption rights, when applicable, would require us to offer new shares for allotment to existing shareholders on a pro rata basis before allotting them to other persons. In such circumstances, the procedure for the exercise of such statutory pre-emption rights would be set out in the documentation by which such ordinary shares would be offered to our shareholders. These statutory pre-emption rights may be disapplied by a special resolution passed by shareholders in a general meeting in accordance with the provisions of the Companies Act 2006.

# **Preferred Shares**

Our board of directors may, from time to time, following an ordinary resolution of the ordinary shareholders granting authority to the directors to allot shares and special resolution of the ordinary shareholders to disapply pre-emption rights (if applicable and not already disapplied), issue preferred shares with such designations, powers, preferences, privileges, and relative participating, optional or special rights as well as the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the ordinary shares, as determined by an ordinary resolution of the ordinary shareholders (or as set out in the articles of association following a special resolution of the ordinary shareholders to amend the articles of association). Holders of preferred shares may be entitled to receive a preference payment in the event of our liquidation before any payment is made to the holders of ordinary shares. There are currently no preferred shares outstanding, and we have no present intention to issue any preferred shares.

#### Directors

Unless and until we in a general meeting of our shareholders otherwise determine, the number of directors shall not be subject to any maximum but shall not be less than two.

#### **General Meetings and Notices**

#### **Annual General Meetings**

We shall in each year hold a general meeting of our shareholders in addition to any other meetings in that year, and shall specify the meeting as such in the notice convening it. The annual general meeting shall be held at such time and place as the directors may appoint.

#### **Calling of General Meetings**

The directors may call a general meeting of shareholders. The directors must call a general meeting if the shareholders and the Companies Act 2006 require them to do so.

#### **Quorum of Meetings**

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business but the absence of a quorum shall not preclude the appointment of a chairman that shall not be treated as part of the business of a meeting. One or more qualifying persons present at a meeting and between them holding (or being the proxy or corporate representative of the holders of) at least one-third in number of the issued shares (excluding any shares held as treasury shares) entitled to vote on the business to be transacted are a quorum. A qualifying person for these purposes is an individual who is a member, a person authorized to act as the representative of a member (being a corporation) in relation to the meeting or a person appointed as proxy of a member in relation to the meeting.

#### Other U.K. Law Considerations

#### **Mandatory Purchases and Acquisitions**

Pursuant to sections 979 to 991 of the Companies Act 2006, where a takeover offer has been made for the Company and the offeror has acquired or unconditionally contracted to acquire not less than 90 percent of the voting rights carried by those shares, the offeror may give notice to the holder of any shares to which the offer relates and which the offeror has not acquired or unconditionally contracted to acquire, that he wishes to acquire and is entitled to so acquire those shares on the same terms as the general offer.

#### Disclosure of Interest in Shares

Pursuant to Part 22 of the Companies Act 2006 and our articles of association, we are empowered by notice in writing to require any person whom we know to be, or have reasonable cause to believe to be, interested in the Company, our shares or, at any time during the three years immediately preceding the date on which the notice is issued has been so interested, within a reasonable time to disclose to us particulars of any interest, rights, agreements or arrangements affecting any of the shares held by that person or in which such other person as aforesaid is interested (so far as is within his knowledge).

Under our articles of association, if a person defaults in supplying us with the required particulars in relation to the shares in question ("default shares"), the directors may by notice direct that:

- · in respect of the default shares, the relevant member shall not be entitled to vote or exercise any other right conferred by membership in relation to general meetings; and/or
- · where the default shares represent at least 0.25 percent of their class, (a) any dividend or other money payable in respect of the default shares shall be retained by us without liability to pay interest, and/or (b) no transfers by the relevant member of shares other than certain approved transfers may be registered (unless the member himself is not in default and the transfer does not relate to default shares), and/or (c) any shares held by the relevant number in uncertificated form shall be converted into certificated form.

#### **Purchase of Own Shares**

Under English law, a public limited company may only purchase its own shares out of the distributable profits of the company or the proceeds of a fresh issue of shares made for the purpose of financing the purchase. A limited company may not purchase its own shares if as a result of the purchase there would no longer be any issued shares of the company other than redeemable shares or shares held as treasury shares.

Subject to the above, we may purchase our own shares in the manner prescribed below. We may purchase on a recognized investment exchange our own fully paid shares pursuant to an ordinary resolution of the Company. The resolution authorizing the purchase must:

- · specify the maximum number of shares authorized to be acquired;
- · determine the maximum and minimum prices that may be paid for the shares; and
- specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

We may purchase our own fully paid shares otherwise than on a recognized investment exchange pursuant to a purchase contract authorized by special resolution of the Company before the purchase takes place. Any authority will not be effective if any shareholder from whom we propose to purchase shares votes on the resolution and the resolution would not have been passed if he had not done so. The resolution authorizing the purchase must specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

# **Takeover Provisions**

If at the time of a takeover offer the U.K. Panel on Takeovers and Mergers (the "Takeover Panel") determines that we have our place of central management and control in the United Kingdom, we would be subject to the U.K. City Code on Takeovers and Mergers (the "Takeover Code"), which is issued and administered by the Takeover Panel. The Takeover Code provides a framework within which takeovers of companies subject to it are conducted, including, in particular, certain rules in respect of mandatory offers.

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.

### **Exchange Controls**

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ordinary shares, other than withholding tax requirements. There is no limitation imposed by English law or our articles of association on the right of non-residents to hold or vote shares.

#### **Market Listing**

Our ADSs are listed on The Nasdaq Global Select Market under the symbol "ADAP."

#### **DESCRIPTION OF AMERICAN DEPOSITARY SHARES**

Citibank, N.A. (the "Depositary") has agreed to act as the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A. London Branch, having its principal office at Citigroup Centre, Canada Square, Canary Wharf, London E14 5LB, England.

We have appointed Citibank as depositary bank pursuant to a deposit agreement. A copy of the deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-6. A copy of the deposit agreement is available from the SEC's website (www.sec.gov). Please refer to Registration Number 333-203642, Registration Number 333-212714 or Registration Number 333-233560 when retrieving such copy.

"Holder" means the person or persons in whose name an ADS is registered on the register maintained by the Depositary for such purpose.

Each ADS represents the right to receive 12 ordinary shares, each of which is frequently referred to as a "Share" or collectively, as "Shares", on deposit with the custodian. An ADS also represents the right to receive any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. Owners of ADSs will be able to exercise beneficial ownership interests in the deposited property only through the registered holders of the ADSs, by the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and by the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary bank. As an ADS holder, you appoint the depositary bank to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of Shares will continue to be governed by the laws of England and Wales, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary bank, the custodian, us nor any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary bank will hold on your behalf the shareholder rights attached to the Shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the Shares represented by your ADSs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

#### **Dividends and Distributions**

Holders generally have the right to receive the distributions we make on the securities deposited with the custodian. A Holder's receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

#### **Distributions of Cash**

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of England and Wales.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

#### **Distributions of Shares**

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will *either* distribute to holders new ADSs representing the ordinary shares deposited *or* modify the ADS-to-ordinary share ratio, in which case each ADS a Holder holds will represent rights and interests in an integral number of the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary share ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (i.e., the U.S. securities laws) or if it is not practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

#### Distributions of Rights

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depositary bank and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, we indicate that we wish such rights to be made available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). A Holder may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of a Holder's rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other than in the form of ADSs.

The depositary bank will *not* distribute the rights to a Holder if:

- · We do not timely request that the rights be distributed to a Holder or we request that the rights not be distributed to a Holder; or
- $\cdot$  We fail to deliver satisfactory documents to the depositary bank; or
- · It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

#### **Elective Distributions**

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to a Holder. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to a Holder only if it is lawful and reasonably practicable, we indicate that we wish such election to be made available to holders of ADSs, and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable a Holder to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to a Holder, such Holder will receive either cash or additional ADSs, upon the terms described above for distributions of cash and ordinary shares, respectively, depending on what a shareholder in England and Wales would receive upon failing to make an election, as more fully described in the deposit agreement.

#### Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to Holders. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to a Holder, we indicate that we wish such distribution to be made available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will *not* distribute the property to a Holder and will sell the property if:

- · We do not request that the property be distributed to a Holder or if we ask that the property not be distributed to a Holder; or
- · We do not deliver satisfactory documents to the depositary bank; or
- The depositary bank determines that all or a portion of the distribution to a Holder is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

#### Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. A Holder may have to pay fees, expenses, taxes and other governmental charges upon the redemption of a Holder's ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary bank may determine.

# **Changes Affecting Ordinary Shares**

The ordinary shares held on deposit for a Holder's ADSs may change from time to time. For example, there may be a change in nominal or par value, a split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, a Holder's ADSs would, to the extent permitted by law, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to a Holder, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of a Holder's existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the depositary bank may not lawfully distribute such property to a Holder, the depositary bank may sell such property and distribute the net proceeds to a Holder as in the case of a cash distribution.

#### **Issuance of ADSs upon Deposit of Ordinary Shares**

The depositary bank may create ADSs on a Holder's behalf if a Holder or a Holder's broker deposit ordinary shares with the custodian. The depositary bank will deliver these ADSs to the person a Holder indicates only after a Holder pays any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. A Holder's ability to deposit ordinary shares and receive ADSs may be limited by U.S. and English legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When a Holder makes a deposit of ordinary shares, a Holder will be responsible for transferring good and valid title to the depositary bank. As such, a Holder will be deemed to represent and warrant that:

- · The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- · All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- · A Holder is duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement).
- · The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at a Holder's cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

#### Transfer, Combination and Split Up of ADRs

ADR Holders will be entitled to transfer, combine or split up such Holder's ADRs and the ADSs evidenced thereby. For transfers of ADRs, a Holder will have to surrender the ADRs to be transferred to the depositary bank and also must:

- · ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- · provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate; provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have a Holder's ADRs either combined or split up, such Holder must surrender the ADRs in question to the depositary bank with such Holder's request to have them combined or split up, and such Holder must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

#### Withdrawal of Ordinary Shares Upon Cancellation of ADSs

ADS Holders will be entitled to present such Holder's ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. A Holder's ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and English considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by a Holder's ADSs, such Holder will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares being withdrawn. A Holder assumes the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

The depositary bank may ask a Holder to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel a Holder's ADSs. The withdrawal of the ordinary shares

represented by a Holder's ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

Holders will have the right to withdraw the securities represented by such Holder's ADSs at any time except for:

- · Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- · Obligations to pay fees, taxes and similar charges; and
- · Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair a Holder's right to withdraw the securities represented by a Holder's ADSs except to comply with mandatory provisions of law.

#### **Voting Rights**

Holders generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by a Holder's ADSs. The voting rights of holders of ordinary shares are described above in "Ordinary Shares—Voting Rights."

At our request, the depositary bank will distribute to a Holder any notices of shareholders' meetings received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs.

If the depositary bank timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with the voting instructions received from such holder and as follows.

- · In the event of voting by show of hands, the Depositary will vote (or cause the custodian to vote) all Shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- · In the event of voting by poll, the Depositary will vote (or cause the custodian to vote) the Shares held on deposit in accordance with the voting instructions received from the holders of ADSs. Under certain limited circumstances described in the deposit agreement, a person designated by us shall be entitled to vote the Shares held on deposit for which voting instructions have not been timely received by the depositary from holders of ADSs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated herein). Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure that Holders will receive voting materials in time to enable such Holder to return voting instructions to the depositary bank in a timely manner.

# **Fees and Charges**

The following table shows the fees and charges that a holder of our ADSs may have to pay, either directly or indirectly. These fees and charges are set by the Depositary and are subject to change:

Service	Fees
Issuance of ADSs	Up to U.S. 5¢ per ADS issued
Cancellation of ADSs	Up to U.S. 5¢ per ADS canceled
Distribution of cash dividends or other cash distributions	Up to U.S. 5¢ per ADS held
Distribution of ADSs pursuant to stock dividends, free stock distributions or exercise of rights	Up to U.S. 5¢ per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held

As an ADS holder you will also be responsible for paying certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges such as:

- · Fees for the transfer and registration of Shares or other deposited securities, including those charged by the registrar and transfer agent for the Shares in England and Wales (i.e., upon deposit and withdrawal of Shares).
- · Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.
- Taxes and duties (including applicable interest and penalties) and other governmental charges, including upon the transfer of securities (i.e., when Shares are deposited or withdrawn from deposit).
- · Fees and expenses as are incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to Shares, deposited securities, ADSs and ADRs.
- · Fees and expenses incurred in connection with the delivery or servicing of Shares and other property on deposit.

Depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The Depositary fees payable for cash distributions are generally deducted from the cash being distributed. In the case of distributions other than cash (i.e., stock dividend, rights), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of a refusal to pay the depositary fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive prior notice of such changes.

The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADS program established pursuant to the deposit agreement, by making available a portion of the depositary fees charged in respect of the ADS program or otherwise, upon such terms and conditions as we and the depositary bank may agree from time to time.

#### **Amendments and Termination**

We may agree with the depositary bank to modify the deposit agreement at any time without a Holder's consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to a Holder's substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges such Holder is required to pay. In addition, we may not be able to provide Holders with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

Holders will be bound by the modifications to the deposit agreement if such Holder's continue to hold ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent a Holder from withdrawing the ordinary shares represented by such Holder's ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to the holders at least 30 days before termination. Until termination, a Holder's rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until a Holder request the cancellation of such Holder's ADSs) and may sell the securities held on deposit. After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

#### **Books of Depositary**

The depositary bank will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

#### **Limitations on Obligations and Liabilities**

The deposit agreement limits our obligations and the depositary bank's obligations to Holders. Please note the following:

- · We and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to Holders on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- · We and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- · We and the depositary bank disclaim any liability if we or the depositary bank are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our articles of association or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- · We and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our articles of association or in any provisions of or governing the securities on deposit.
- We and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- · We and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to Holders.
- · We and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- · We and the depositary bank also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- · No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

#### Taxes

A Holder will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split-up or combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

#### **Foreign Currency Conversion**

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practicable or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- · Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- · Hold the foreign currency (without liability for interest) for the applicable holders.

#### **Governing Law/Waiver of Jury Trial**

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of England and Wales. As an owner of ADSs, holders irrevocably agree that any legal action arising out of the Deposit Agreement, the ADSs or the ADRs, involving the Company or the Depositary, may only be instituted in a state or federal court in the city of New York.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**EXECUTION COPY** 

# COLLABORATION AND LICENSE AGREEMENT BY AND BETWEEN UNIVERSAL CELLS, INC. ADAPTIMMUNE LIMITED

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#### COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the "Agreement") dated January 13, 2020 (the "Effective Date") is by and between UNIVERSAL CELLS, INC. a corporation organized and existing under the laws of the state of Washington and having its principal office at 3005 1st Avenue Seattle, WA 98121 ("Universal Cells") and ADAPTIMMUNE LIMITED, a company incorporated in England and Wales and with its registered address at 101 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY ("Adaptimmune"). Each of Universal Cells and Adaptimmune are referred to as a "Party", and Universal Cells and Adaptimmune are collectively referred to as the "Parties."

#### INTRODUCTION

**WHEREAS**, Universal Cells and Adaptimmune are parties to that certain Research Collaboration and License Agreement dated November 25th, 2015, as amended (and for clarity including the sublicenses set forth in Schedules 2 and 3 attached thereto) (the "**Existing Agreement**") regarding the research, development, and commercialization of products using or incorporating certain gene-edited induced pluripotent stem cell lines for use in immunotherapy applications.

**WHEREAS**, Astellas Pharma Inc. ("**Astellas**") acquired Universal Cells and Universal Cells is now a wholly-owned subsidiary of Astellas.

**WHEREAS**, the Parties now desire to collaborate to research, develop, and commercialize certain cellular therapy products directed to certain targets, and Universal Cells desires to obtain certain exclusive rights and licenses to research, develop, and commercialize certain cellular therapy products directed to other selected targets, in each case, on the terms and conditions set forth herein.

**NOW, THEREFORE**, the Parties agree as follows:

# **ARTICLE 1**

# **DEFINITIONS**

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article 1:

- **1.1** "Active Research Program" means a research program relating to Cells that is being conducted by or on behalf of Adaptimmune or its Affiliates outside the scope of the Collaboration for which Adaptimmune or its Affiliates has [\*\*\*].
- **1.2 "Adaptimmune Background IP"** means all Patent Rights and Know-How Controlled by Adaptimmune as of the Effective Date or that comes into the Control of Adaptimmune during the Term, other than Collaboration Inventions and Patent Rights covering such inventions. Adaptimmune Background IP includes Adaptimmune-Licensed Universal Cells IP.

# **1.3** "Adaptimmune-Licensed IP" means:

- **1.3.1** with respect to any Unilateral Universal Cells Product, all (i) Adaptimmune Background IP and (ii) Arising IP Controlled by Adaptimmune, in each case of (i) and (ii), that is necessary or reasonably useful for Universal Cells to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit the Unilateral Universal Cells Product in the Field in the Territory, as such Product exists when such Product transitions from a Collaboration Product to a Unilateral Universal Cells Product as set forth in this Agreement;
- **1.3.2** with respect to any Collaboration Product, all (i) Adaptimmune Background IP and (ii) Arising IP Controlled by Adaptimmune, in each case of (i) and (ii), that is necessary or reasonably useful for Universal Cells to make, have made, use, sell, offer for sale, import, export, Develop, Commercialize, and otherwise exploit such Collaboration Product.
- **1.4 "Adaptimmune-Licensed Universal Cells IP"** means Patent Rights and Know-How Controlled by Universal Cells and licensed to Adaptimmune pursuant to the Existing Agreement (and thereby Controlled by Adaptimmune for purposes of this Agreement) during the Term of this Agreement.
- **1.5 "Adaptimmune Technology"** means Adaptimmune's proprietary technologies consisting of any of the following, or any combination of the following: [\*\*\*].
- **1.6 "Adaptimmune Technology Inventions"** means Collaboration Inventions that relate solely to the Adaptimmune Technology, whether generated solely by or on behalf of Universal Cells or Adaptimmune or jointly by or on behalf of the Parties.
- **1.7 "Affiliate"** means any corporation, company, partnership, joint venture, or firm that controls, is controlled by, or is under common control with a specified person or entity. For purposes of this Section 1.7, "control" shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. For clarity, Astellas and Universal Cells shall be considered Affiliates of each other.
- **1.8 "Applicable Law"** means the applicable laws, rules, and regulations in any jurisdiction in the world, including any rules, regulations, guidelines, or other requirements of the Governmental Authorities that may be in effect from time to time and, in each case, to the extent they apply to a Party's performance of its obligations or exercise of its rights under this Agreement. Applicable Law shall include compliance with GCP, GLP, and GMP, as applicable.
- **1.9 "Arising Collaboration IP"** means all Patent Rights covering the Collaboration Inventions and all Know-How included in the Collaboration Inventions.
  - **1.10** "Arising IP" means the Arising Collaboration IP and the Arising Universal Cells Program IP.

- **1.11 "Arising Universal Cells Program IP"** means all Patents Rights covering and Know-How included in the Universal Cells Program Inventions.
- **1.12 "Calendar Quarter"** means each of the three (3) month periods ending March 31, June 30, September 30, and December 31; *provided*, *however*, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter shall extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.
- **1.13 "Calendar Year"** means each of the twelve (12) month periods ending December 31; *provided*, *however*, that: (a) the first Calendar Year of the Term shall extend from the Effective Date to the end of the first complete Calendar Year thereafter; and (b) the last Calendar Year shall extend from the beginning of the Calendar Year in which this Agreement expires or terminates until the effective date of such expiration or termination.
  - **1.14 "CAR"** means a chimeric antigen receptor. For clarity, a CAR is a Receptor.
  - **1.15 "CAR-T Cell"** means a T-Cell expressing a CAR.
- **1.16 "Cell"** means autologous or pluripotent stem cell-derived T-Cells (including NK-T Cells, TCR-T Cells, and CAR-T Cells). For clarity, an NK Cell shall not be considered a Cell.
- 1.17 "Change of Control" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning fifty percent (50%) or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve a plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party's assets, other than to an Affiliate or pursuant to a transaction that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (d) the sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole.
- **1.18 "Co-Commercialization Plan"** means each written plan governing the co-Commercialization of each Collaboration Profit-Share Product.
- **1.19 "Co-Commercialization Program"** means the co-Commercialization activities to be conducted by the Parties for each Collaboration Profit-Share Product in accordance with the applicable Co-Commercialization Plan.

- **1.20 "Co-Development Plan"** means each written plan governing the co-Development of each Collaboration Profit-Share Product.
- **1.21 "Co-Development Program"** means the co-Development activities to be conducted by the Parties for each Collaboration Profit-Share Product in accordance with the applicable Co-Development Plan.
- **1.22** "Collaboration" means the collaborative Development, Manufacturing, and Commercialization activities to be conducted by the Parties pursuant to this Agreement with respect to Collaboration Products (including Collaboration Profit-Share Products) as well as with respect to the activities conducted under the Pre-Designation Research Collaboration, but excluding in all cases the activities conducted by Universal Cells with respect to the Universal Cells Program or by either Party with respect to Unilateral Products.
- **1.23 "Collaboration Inventions"** means all inventions, discoveries, Know-How, and improvements generated in the course of performing activities (a) under the Collaboration Research Programs, Co-Development Programs, or Co-Commercialization Programs, or (b) with respect to Unilateral Products. Collaboration Inventions include the Adaptimmune Technology Inventions, PSC Inventions, Collaboration Joint Inventions, and Universal Cells Technology Inventions. Collaboration Inventions exclude Universal Cells Program Inventions.
- **1.24** "Collaboration Joint Invention" means any Collaboration Invention, whether generated solely by or on behalf of Universal Cells or Adaptimmune or jointly by the Parties, that (a) is not an Adaptimmune Technology Invention, PSC Invention, or Universal Cells Technology Invention, (b) includes a combination of Adaptimmune Technology Inventions and Universal Cell Technology Inventions, or (c) relates to one or more of (i) [\*\*\*], (ii) [\*\*\*], or (iii) any methods of treatment using a Collaboration Product.
- **1.25 "Co-Medical Affairs Plan"** means each written plan governing the Medical Affairs Activities of each Collaboration Profit-Share Product.
- **1.26 "Collaboration Product"** means any Product Directed To a Collaboration Target. Collaboration Products include all Collaboration Profit-Share Products, but do not include Unilateral Products or Lapsed Products.
- **1.27 "Collaboration Profit-Share Product"** means any Collaboration Product Directed To a Collaboration Profit-Share Target.
- **1.28** "Collaboration Profit-Share Target" means a Collaboration Target for which each Party provides the other Party a Continuing Development and Commercialization Notice in accordance with Section 4.10.2 (Collaboration Profit-Share Products and Targets).
- **1.29** "Collaboration Research Plan" means each written plan governing the conduct of all Development activities to be conducted by the Parties for each Collaboration Product Directed To a Collaboration Target, through the completion of the first Phase 1 Clinical Trial and prior to the designation of such Collaboration Product as Collaboration Profit-Share Product, which may include (a) identifying and characterizing such Collaboration Targets and such Collaboration Product, and (b) thereafter perform further nonclinical and pre-clinical Development

activities with respect to such Collaboration Target and Collaboration Product, including the associated Collaboration Research Plan Budget.

- **1.30 "Collaboration Research Program"** means all Development activities to be conducted by the Parties for a Collaboration Target and a Collaboration Product Directed To such Collaboration Target in accordance with the applicable Collaboration Research Plan.
- **1.31 "Collaboration Research Term"** means, for a given Collaboration Target and the relevant Collaboration Product containing an engineered Receptor Directed To such Collaboration Target, unless otherwise agreed in writing by the Parties, the period of time starting on the designation of such Collaboration Target pursuant to Section 3.3 (Designation of Nominated Targets) and ending upon the earlier of (a) completion of the first Phase 1 Clinical Trial for a Collaboration Product Directed To such Collaboration Target or (b) [\*\*\*] years after the designation of such Collaboration Target.
- **1.32 "Collaboration Target"** means a Target nominated and designated in accordance with Article 3 (Pre-Designation Research Program) or Section 4.6 (Target Substitution) for which a Receptor Directed To such Target will be introduced into a Cell under the Collaboration. Collaboration Targets include all Collaboration Profit-Share Targets.
- 1.33 "Commercialize" means any and all processes and activities conducted to establish and maintain sales for products, including (a) to conduct post-marketing surveillance studies required by a Regulatory Authority and to market, advertise, promote, distribute, import, export, offer to sell (including pricing and reimbursement and value and access activities as well as observational research and evidence generation), detail or sell products and (b) activities in support of any of the foregoing (including training, materials, public relations and market research). "Commercialization" shall have the correlative meaning with respect to such activities. Commercialize and Commercialization each expressly excludes Medical Affairs Activities and Development and Manufacturing activities (including Manufacturing activities related to Commercialization).
- 1.34 "Commercially Reasonable Efforts" means with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. With respect to any efforts relating to the Development, Regulatory Approval, Manufacture or Commercialization of a Product by a Party, generally or with respect to any particular country in the Territory, a Party will be deemed to have exercised Commercially Reasonable Efforts if such Party has exercised those efforts normally used by such Party, in the relevant country, with respect to a product or product candidate of similar modality owned or controlled by such Party, or to which such Party has similar rights, which product or product candidate is of similar market potential in such country, and is at a similar stage in its development or product life cycle as the Product, taking into account all Relevant Factors in effect at the time such efforts are to be expended. To the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

- **1.35 "Competitive Product"** means, with respect to a Collaboration Profit-Share Product, Unilateral Product, or Universal Cells Program Product, as applicable, [\*\*\*].
- **1.36 "Confidential Information"** of a Party means all Know-How, unpublished patent applications, and other confidential or proprietary information and data of a Party, including that of a financial, commercial, business, operational, or technical nature, that is disclosed by or on behalf of such Party or otherwise made available to, or otherwise learned by, the other Party, whether made available orally, in writing, or in electronic form, in each case, in the performance of activities under this Agreement.
- "Control" or "Controlled" means, with respect to any Know-How or Patent Right, the possession 1.37 (whether by ownership or license, other than through the grant of a license under this Agreement) by a Party of the legal ability and authority to grant to the other Party a license or access as provided herein to such Know-How or Patent Right, without violating the terms of any agreement or other arrangement of such Party with any Third Party in existence as of the time such Party would first be required hereunder to grant the other Party such license or access or such Party being obligated to pay any royalties or other consideration in connection with the grant of such rights; provided, however, if (a) a Party would Control any Know-How or Patent Right but for an obligation to pay royalties or other consideration in connection with a grant to the other Party of rights under such Know-How or Patent Right and (b) the other Party agrees in writing to reimburse the first Party for all such royalties or other consideration, then such Know-How or Patent Right shall be deemed Controlled by the first Party for purposes of this Agreement. Notwithstanding the foregoing, a Party will not be deemed to "Control" any Patent Right or Know-How that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party after the Effective Date as a result of such Change of Control unless (i) prior to the consummation of such Change of Control, such acquired Party or any of its Affiliates also Controlled such Patent Right or Know-How, or (ii) the Know-How or Patent Rights owned or in-licensed by the applicable Third Party were not used in the performance of activities in the course of the Collaboration or with respect to Unilateral Products or Elected Universal Cells Program Products prior to the consummation of such Change of Control, but after the consummation of such Change of Control, such acquired Party or any of its Affiliates determines to use or uses any such Patent Rights or Know-How in the performance of activities in the course of the Collaboration or with respect to Unilateral Products or Elected Universal Cells Program Products, in each of which cases ((i) and (ii)), such Patent Rights or Know-How will be "Controlled" by such Party for purposes of this Agreement.
- 1.38 "Develop" means all research and development activities for any pharmaceutical or biological product that are directed to obtaining or maintaining Regulatory Approval(s) of such product and lifecycle management of such Product in any country in the world (whether conducted prior to or following receipt of Regulatory Approval for such product in the applicable jurisdiction), including all nonclinical, preclinical, and clinical testing and studies of such product; toxicology, pharmacokinetic, and pharmacological studies; statistical analyses; assay development; protocol design and development; the preparation and submission of any MAAs for such product; development activities directed to label expansion or obtaining Regulatory Approval for one or more additional indications following receipt of Regulatory Approval for an initial indication; and all regulatory affairs activities related to any of the foregoing. "Development" shall have the correlative meaning with respect to such activities. Develop and Development each

expressly excludes Medical Affairs Activities and Commercialization and Manufacturing activities (including Manufacturing activities related to Development).

- **1.39 "Directed To"** means, with respect to a Receptor and a Target, that such Receptor has been developed or engineered to bind or interact with such Target and is specific to such Target, irrespective of whether it also binds or interacts with any other Target(s) otherwise non-specifically.
- 1.40 "Elected Unilateral Adaptimmune Product Royalty Term" means, on a per-Elected Unilateral Adaptimmune Product and per-country basis, the period beginning on the First Commercial Sale of such Elected Unilateral Adaptimmune Product in such country until the later of (a) the expiration of the last-to-expire Valid Claim of the Patent Rights within the Arising IP Controlled by Universal Cells (whether solely or jointly) covering Contributed Technology used in or was contained in such Elected Unilateral Adaptimmune Product that is licensed to Adaptimmune pursuant to the Elected Unilateral Adaptimmune Product License or (b) [\*\*\*] after the First Commercial Sale of such Elected Unilateral Adaptimmune Product in such country.
- **1.41 "Elected Unilateral Adaptimmune Products"** means all Unilateral Adaptimmune Products that use, contain, or incorporate Contributed Technology and are Directed To an Elected Unilateral Adaptimmune Target specified in an Unilateral Adaptimmune Product Elected License Notice.
- **1.42 "Elected Universal Cells Program Product"** means a Universal Cells Program Product Directed To a particular Elected Universal Cells Program Target specified in a Universal Cells Program Product Elected License Notice.
- 1.43 "Elected Universal Cells Program Product Royalty Term" means, on a per-Elected Universal Cells Program Product and per-country basis, the period of time beginning on the First Commercial Sale of such Elected Universal Cells Program Product in such country and ending on the later of (a) expiration of the last-to-expire Valid Claim of the (i) Patent Rights Controlled by Adaptimmune (other than by means of the licenses granted by Universal Cells to Adaptimmune pursuant to this Agreement or the Existing Agreement) and licensed to Universal Cells pursuant to an Elected Universal Cells Program Product License or (ii) Patent Rights covering any Collaboration Joint Inventions, in each case of ((i) and (ii)), covering such Elected Universal Cells Program Product or (b) [\*\*\*] years after the First Commercial Sale of such Elected Universal Cells Program Product in such country.
- **1.44 "Excluded Target"** means any Target with respect to which, as of the date such Target is nominated for designation as a Collaboration Target or Universal Cells Program Target, [\*\*\*]. For clarity, to the extent a Target ceases to meet any of the criteria of (a), (b), or (c) during the period between the Effective Date and the Target Identification and Tracking End Date, Target shall immediately cease to be an Excluded Target and shall become a Target eligible for nomination and designation (the "**Non-Excluded Target"**), unless and until any of (a) through (c) again apply prior to the date on which such Non-Excluded Target is nominated for designation as a Collaboration Target or Universal Cells Program Target..

- **1.45 "Executive Officers"** means the President of Universal Cells or an Affiliate of Universal Cells (or an executive of Universal Cells designated by such President) and the Chief Executive Officer of Adaptimmune (or an executive of Adaptimmune designated by such Chief Executive Officer).
- **1.46 "Expert"** means an independent Third Party mutually agreeable to the Parties to be engaged for the purpose of confirming whether a Target nominated as a Collaboration Target or a Universal Cells Program Target (as applicable) can be designated as such or whether such Target is an Excluded Target pursuant to Section 3.3 (Designation of Nominated Targets). The Expert shall be someone who possesses substantial experience in biopharmaceutical research and development activities and agreements relating thereto and agrees to be bound by a non-disclosure agreement acceptable to both Parties.
  - **1.47 "FDA"** means the United States Food and Drug Administration, or a successor agency thereto.
  - **1.48 "Field"** means the treatment of human diseases and conditions using Cell-based immunotherapy.
- **1.49 "First Commercial Sale"** means, for a given Product in a given country, the first sale for end use or consumption of such Product in such country after Regulatory Approval has been granted in such country. Sales for clinical trial purposes or compassionate or similar uses at [\*\*\*] or less of the cost of goods sold thereof shall not be considered to constitute a First Commercial Sale.
- **1.50 "FTE"** means a full-time equivalent person (*i.e.*, one fully-dedicated or multiple partially-dedicated employees aggregating to one full-time employee) employed or contracted by a Party or its Affiliates based upon a total of [\*\*\*] per year undertaken in connection with the conduct of Development, Commercialization, Manufacturing, or Medical Affairs Activities in furtherance of the Collaboration. Overtime, and work on weekends, holidays, and the like shall not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.
  - **1.51 "FTE Rate"** means [\*\*\*] per FTE per year inclusive of direct costs [\*\*\*].
- **1.52 "Gene Editing Technology"** means the [\*\*\*], as developed by or on behalf of Universal Cells prior to the Effective Date of this Agreement or outside of the performance of this Agreement.
- **1.53 "Good Clinical Practices"** or **"GCP"** means the standards, practices, and procedures set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA or any successor agency thereto and, as applicable, comparable regulatory standards in jurisdictions outside of the United States.
- **1.54 "Good Laboratory Practices"** or **"GLP"** means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and, as applicable, comparable regulatory standards in jurisdictions outside of the United States.

- **1.55 "Good Manufacturing Practices"** or **"GMP"** means the then-current good manufacturing practices required by the FDA or any successor agency thereto and set forth in the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, for the Manufacturing and testing of pharmaceutical materials, and, as applicable, any other comparable regulatory standards applicable to the Manufacturing and testing of pharmaceutical materials in jurisdictions outside of the United States.
- **1.56 "Governmental Authority"** means any tribunal, court, agency, department, authority, or other instrumentality of any national, state, county, city, or other political subdivision.
- **1.57 "HLA Engineering Technology"** means [\*\*\*] as developed prior to the Effective Date or outside of the performance of this Agreement.
- **1.58** "IND" means (a) (i) an Investigational New Drug Application, as defined in the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder, that is required to be filed with the FDA before beginning clinical testing of a pharmaceutical or biological product in human subjects, or any successor application or procedure or (ii) any comparable application in any jurisdiction outside of the United States, and (b) all supplements and amendments that may be filed with respect to the foregoing.
  - **1.59** "Initial Edited Cell Line" means the [\*\*\*].
- **1.60 "Know-How"** means proprietary, non-public techniques, technology, formulations, practices, trade secrets, inventions (whether patentable or not), methods, know-how, records, data and results (including pharmacological, toxicological, and clinical data and results), analytical and quality control data and results, regulatory documents and other information, compositions of matter, cells, cell lines, assays, animal models, reagents, and other physical, biological, or chemical material, in each case, whether or not patentable.
  - **1.61 "Lapsed Product"** means a Product Directed To a Lapsed Target.
- **1.62 "Lapsed Target"** means a former Collaboration Target that becomes so in accordance with Section 4.6.3 (Effects of Substitution) or Section 4.10.4 (Lapsed Products and Targets).
- **1.63 "MAA"** means a marketing authorization application filed with a Regulatory Authority seeking Regulatory Approval to market and sell any Product for a particular indication in a regulatory jurisdiction under the authority of such Regulatory Authority. By way of example only, a MAA in the United States for a biologic product is a Biologics License Application (as that term is used in Title 21 of the United States Code of Federal Regulations).
  - **1.64** "Major EU Country" means France, Germany, Italy, Spain, and the United Kingdom.
  - **1.65** "Major Market" means the United States, Japan, and any Major EU Country.
- **1.66 "Manufacturing"** means any and all processes and activities directed to producing, manufacturing, processing, sourcing of materials for, filling, finishing, packaging, labeling,

inspecting, quality assurance testing and release, receiving, holding, shipping, or storage of clinical or commercial products (or any raw materials or packaging materials with respect thereto, or any intermediate of any of the foregoing), including process and cost optimization, process qualification and validation, stability and release testing, and quality control. "Manufacture" shall have the correlative meaning with respect to such activities. Manufacturing and Manufacture each expressly excludes Medical Affairs Activities and Development and Commercialization activities.

- 1.67 "Medical Affairs Activities" means design, strategies, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or further research regarding, a product, including activities of Medical Liaisons, grants to support continuing independent medical education (including independent symposia, and congresses), and development, publication and dissemination of scientific and clinical information, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or other external-facing representatives or received by letter, phone call or email or other means of communication.
- **1.68 "Medical Liaison"** means those health care professionals employed or engaged by a Party or any of its Affiliates with appropriate health care experience to engage in in-depth dialogues with physicians regarding medical issues associated with a product, and are not sales representatives or otherwise engaged in Commercialization of a product.
- **1.69** "Net Sales" means, with respect to a given Product or Competitive Product, the gross invoiced sales prices charged for a Product or Competitive Product (after Regulatory Approval of such Product or Competitive Product) sold by a given Party, its Affiliates and sublicensees (the "Selling Party") in arm's length transactions to Third Parties (but not including sales by and among the Selling Parties) during such time period, less the total of the following charges or expenses, as determined in accordance with international financial reporting standards, consistently applied across all products sold by a given Party:
- **1.69.1** Trade, cash, prompt payment or quantity discounts, including promotional, service or similar discounts;
- **1.69.2** Returns, allowances, rebates, chargebacks, other allowances, or payments to government agencies, including any amounts that are imposed or are due under Section 9008 of the U.S. Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and are reasonably allocable to such Product or Competitive Product;

- **1.69.4** Fees paid to distributors, selling agents (excluding any sales representatives of a Selling Party), group purchasing organizations and managed care entities;
  - **1.69.5** Credits or allowances for Product or Competitive Product replacement, whether cash or trade;
- **1.69.6** Non-recoverable sales taxes, excise taxes, tariffs, and duties (excluding taxes when assessed on income derived from sales);

**1.69.8** freight or other transportation charges, insurance charges, additional special packaging, and governmental charges.

Any transfer or disposal of Products or Competitive Product for, or use of Products or Competitive Product in, clinical or pre-clinical trials, given as free samples, or distributed at no charge to indigent patients shall not be included in Net Sales.

Upon any sale or other disposal of a Product that should be included within Net Sales for any consideration other than an exclusively monetary consideration on bona fide arm's length terms, then for purposes of calculating the Net Sales under this Agreement, such Product or Competitive Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Product or Competitive Product in the country in which such sale or other disposal occurred when such Product or Competitive Product is sold alone and not with other products. In the event no sales price is available for the Product or Competitive Product alone in such country during the applicable reporting period, then such Product or Competitive Product shall be deemed to be sold exclusively for money at the arithmetic mean sales price during the applicable reporting period generally achieved for such Product or Competitive Product in all countries in which such sale or other disposal occurred when such Product or Competitive Product is sold alone and not with other products (provided, however, that if such Product or Competitive Product is not sold alone in any country, then the Selling Party shall calculate in good faith a hypothetical market price for the Product or Competitive Product, allocating the same proportion of costs, overhead and profit as are then allocated to all similar substances then being made and marketed by the Selling Party and having an ascertainable market price; provided, however, that if the non-Selling Party in good faith disputes the Selling Party's calculation, the Parties shall resolve the matter in accordance with Article 14 (Dispute Resolution).

If a Product or Competitive Product either (1) is sold in the form of a combination product containing both a Product or Competitive Product with no other active pharmaceutical or therapeutic ingredient(s) (a "Base Product") as well as one or more active pharmaceutical or therapeutic ingredient(s) as separate molecular entity(ies) that are not a Product or Competitive Product (an "Other Component"); or (2) is sold in a form that is any combination of a Base Product and another pharmaceutical or therapeutic product that contains at least one Other Component, where such Base Product or Other Component are not formulated together but are sold together (e.g., bundled) as a single product and invoiced as one product (in either case ((1) or (2)), a "Combination Product"), then the Net Sales of such Combination Product for the purpose of calculating payments owed under this Agreement for sales of such Combination Product, shall be determined as follows: first, Selling Party shall determine the actual Net Sales of such Combination Product (using the above provisions) and then such amount shall be multiplied by the fraction A/(A+B), where A is the invoice price of such Base Product, if sold separately, and B is the total invoice price of the Other Component if sold separately. If the Other Component is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction A/C where A is the invoice price of such Base Product if sold separately and C is the invoice price of such Combination Product. If the Product is not sold separately but the Other Component is sold separately, then Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction 1-B/C where B is the invoice price of the Other

Component if sold separately and C is the invoice price of such Combination Product. If neither such Base Product nor the Other Component is sold separately, then the adjustment to Net Sales shall be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of such Base Product in such Combination Product to the total fair market value of such Combination Product.

Notwithstanding the foregoing, Net Sales shall not include amounts received (whether actually existing or deemed to exist for purposes of calculation) for Product or Competitive Products not packaged for commercial use or distributed for use in clinical trials.

- **1.70 "NK Cell"** means a natural killer cell. For clarity, an NK Cell is not an NK-T Cell.
- **1.71** "NK-T Cell" means a lymphocyte with detectable surface expression of CD3, CD56, and a naturally occurring TCR from an endogenous loci. For clarity, an NK-T Cell is not an NK Cell.
- **1.72 "Other Unilateral Adaptimmune Product Royalty Term"** means, on a per-Other Unilateral Adaptimmune Product and per-country basis, the period of time beginning on the First Commercial Sale of such Other Unilateral Adaptimmune Product in such country until [\*\*\*].
- **1.73 "Other Unilateral Adaptimmune Products"** means Unilateral Adaptimmune Products that are not Elected Adaptimmune Unilateral Products.
- **1.74 "Other Universal Cells Program Product Royalty Term"** means, on a per-Other Universal Cells Program Product and per-country basis, the period of time beginning on the First Commercial Sale of such Other Universal Cells Program Product in such country until the [\*\*\*] anniversary thereof.
- **1.75 "Other Universal Cells Program Product"** means Universal Cells Program Products that are not Elected Universal Cells Program Products.
- **1.76 "Out of Pocket Costs"** means direct costs paid or payable to Third Parties that are specifically identifiable and incurred by a Party or its Affiliates in furtherance of the Development, Manufacture, Medical Affairs Activities, or Commercialization of Collaboration Products, expressly excluding items covered by the FTE Rate; provided, however, that such expenses shall have been documented in accordance with a Party or its Affiliates' accounting standards and shall not include any pre-paid amounts or capital expenditures that are not pre-approved by the JSC, or items intended to be covered by the FTE Rate.
- **1.77 "Patent Rights"** means (a) all patents, priority patent filings, and patent applications, and (b) any divisional, continuation (in whole or in part), or request for continued examination of any of such patents and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reviews, reexaminations, extensions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
- **1.78 "Phase 1 Clinical Trial"** means a human clinical trial of a pharmaceutical or biological product, (a) the principal purpose of which is a preliminary determination of safety,

tolerability, pharmacological activity, pharmacodynamics or pharmacokinetics and recommended dose of a study drug in a Phase 2 clinical trial healthy individuals or patients, and which may include expansion to estimate activity in a specific patient cohort, or similar clinical study prescribed by the Regulatory Authorities, and (b) that satisfies the requirements of 21 C.F.R. § 312.21(a) or its equivalent in jurisdictions outside of the United States. For clarity, Phase 1 Clinical Trial includes Phase 1a, Phase 1b, Phase 1b/2, Phase 1/2a, Phase 1/2, and all other clinical trial categories that include a Phase 1 arm.

- 1.79 "Pivotal Clinical Trial" means a human clinical trial of a pharmaceutical or biological product: (a) with a defined dose or a set of defined doses of such product designed to establish statistically significant efficacy and safety of such product for the purpose of enabling the preparation and submission of a MAA to the competent Regulatory Authorities in a country; (b) that would otherwise satisfy requirements of 21 CFR 312.21(c), or its equivalent in jurisdictions outside of the United States; or (c) that is intended to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which clinical study is a registration trial intended to be sufficient for a first Regulatory Approval (conditional or otherwise), as evidenced by (i) an agreement with or statement from the applicable Regulatory Authority on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the applicable Regulatory Authority, for such registration trial.
- **1.80 "Pre-Designation Research Collaboration"** means the research and other activities to be conducted by the Parties pursuant to Article 3 (Pre-Designation Research Program) regarding the identification, nomination, and designation of Targets as Collaboration Targets or Universal Cells Program Targets.
  - **1.81 "Product"** means any product containing or comprising of a Cell Directed To a Target.
- **1.82** "PSC" means (a) an induced pluripotent stem cell or embryonic stem cell line, either as a parental unedited line that is provided by Universal Cells (including the [\*\*\*]) for use in the Collaboration, or (b) the Universal Cells Collaboration Edited Cell Line, provided that such cell line under either (a) or (b) is not and has not been modified using Adaptimmune Technology.
- **1.83 "PSC Inventions"** means Collaboration Inventions that relate solely to any PSC cell line for use in producing or developing a Collaboration Product (including any Collaboration Profit-Share Product) or Unilateral Product, whether generated solely by or on behalf of Universal Cells or Adaptimmune or jointly by the Parties.
- **1.84 "Receptor"** means a molecule or moiety that is engineered, modified, inserted, or appended in, into, or to a Cell (or the relevant autologous or pluripotent stem cell precursor thereof prior to differentiation into such Cell) and that capable of binding to a Target. A single Receptor that binds to two or more Targets is nevertheless a single Receptor.
  - **1.85** "**Receptor Class**" means either (i) TCRs or (ii) Receptors that are not TCRs.
- **1.86 "Regulatory Approval"** means any and all approvals (including all applicable governmental price and reimbursement approvals), licenses, registrations, or authorizations of any

federal, national, multinational, state, provincial or local Governmental Authority or other authority necessary for the Manufacture, use, storage, import, transport, promotion, marketing, or sale of a pharmaceutical or biological product in a country or regulatory jurisdiction. Regulatory Approval includes approval of any MAA.

- **1.87 "Regulatory Authority"** means any Governmental Authority or other authority responsible for granting Regulatory Approvals for pharmaceutical or biological products, including the FDA and any corresponding national or regional regulatory authorities.
- Approval, Manufacture, or Commercialization of a pharmaceutical product, including (as applicable): actual and potential issues of safety, efficacy or stability; product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected Development, Regulatory Approval, Manufacturing, and Commercialization costs, any issues regarding the ability to manufacture or have manufactured the pharmaceutical product; the likelihood of obtaining Regulatory Approvals (including satisfactory reimbursement or pricing approvals); the timing of such approvals; the regulatory environment and the current and projected regulatory status; labeling or anticipated labeling; the then-current competitive environment and the likely competitive environment at the time of projected entry into the market; past performance of the pharmaceutical product or similar products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; pricing or reimbursement changes due to budget or debt constraints or currency issues in relevant countries; proprietary position, strength and duration of patent protection and anticipated exclusivity; and other relevant scientific, technical, operational and commercial factors.
- **1.89 "Substitution Target"** means a Collaboration Substitution Target or Universal Cells Substitution Target, as applicable.
- **1.90 "Tables, Figures, and Listings"** means, for the first Phase 1 Clinical Trial for a Collaboration Product that is the subject of each Collaboration Research Program, the data and information of the nature set forth on Schedule 1.90.
- **1.91 "Target"** means a protein or biological molecule and all peptides contained within or derived from such protein or biological molecule, provided that a genetic variant of such protein, biological molecule, or peptide shall be considered a distinct Target. [\*\*\*].
- **1.92 "Target Identification and Tracking End Date"** means the date on which all Target Substitution Rights have been exercised or lapsed in accordance with Section 4.6 (Target Substitution) and (a) three (3) [\*\*\*] Collaboration Targets have been designated and (b) two (2) Universal Cells Program Targets have been designated.
- **1.93 "T-Cell"** means a lymphocyte with detectable surface expression of CD3, and one or both of CD4 and CD8 from an endogenous loci.
  - **1.94 "TCR"** means T-cell receptor. For clarity, a TCR is a Receptor.
  - **1.95 "TCR-T Cell"** means a T-Cell expressing a TCR.

- **1.96 "Territory"** means worldwide.
- **1.97 "Third Party"** means any person or entity other than a Party or any of its Affiliates.
- **1.98 "Third Party Existing License"** means a *bona fide* agreement as between Adaptimmune and a Third Party pursuant to which [\*\*\*].
- **1.99 "Unilateral Adaptimmune Product"** means the Product Directed To a Unilateral Adaptimmune Target.
- **1.100 "Unilateral Adaptimmune Target"** means a former Collaboration Target that becomes so in accordance with Section 4.10.3(b) (Unilateral Adaptimmune Product) or Section 13.2.2 (Termination for Convenience).
- **1.101 "Unilateral Product"** means a Unilateral Universal Cells Product or a Unilateral Adaptimmune Product, as applicable.
  - **1.102** "Unilateral Target" means a Unilateral Universal Cells Target or a Unilateral Adaptimmune Target.
- **1.103 "Unilateral Universal Cells Product"** means the Product Directed To a Unilateral Universal Cells Target.
- **1.104** "Unilateral Universal Cells Product Royalty Term" means, on a per-Unilateral Universal Cells Product and per-country basis, the period of time beginning on the First Commercial Sale of such Unilateral Universal Cells Product in such country and ending on the later of (a) the expiration of the last-to-expire Valid Claim of the (i) Patent Rights Controlled by Adaptimmune (other than by means of the licenses granted by Universal Cells to Adaptimmune pursuant to the Agreement or the Existing Agreement) and licensed to Universal Cells pursuant to Section 9.1.4 (Unilateral Universal Cells Product License) or (ii) Patent Rights within the Collaboration Joint Inventions, in each case of (i) and (ii), covering such Unilateral Universal Cells Product ("Licensed Unilateral Universal Cells Product Patent") or (b) [\*\*\*] after the First Commercial Sale of such Unilateral Universal Cells Product in such country.
- **1.105 "Unilateral Universal Cells Target"** means a former Collaboration Target which becomes so deemed in accordance with Section 4.10.3(a) (Unilateral Universal Cells Product), Section 5.3 (Development of and Clinical Trials for Collaboration Profit-Share Products), or Section 13.3.2 (Termination for Convenience for Unilateral Adaptimmune Targets).
- **1.106** "Universal Cells Background IP" means all Patent Rights and Know-How Controlled by Universal Cells as of the Effective Date or that comes into the Control of Universal Cells during the Term, other than Collaboration Inventions and Know-How arising from the Collaboration.
- **1.107** "Universal Cells Grant-Back Patent Rights" means all Patent Rights included in the Arising Universal Cells Program IP Controlled by Universal Cells that (a) [\*\*\*] and (b) [\*\*\*].

**1.108** "Universal Cells Collaboration Edited Cell Line" means (a) [\*\*\*] or (b) the [\*\*\*], and in each case (a) and (b), which does not contain any Adaptimmune Technology.

# 1.109 "Universal Cells Licensed IP" means:

- **1.109.1** With respect to any Unilateral Adaptimmune Product, (i) Universal Cells Background IP (excluding any Background IP relating to the Contributed Technology) and (ii) all Arising Collaboration IP that does not relate to the Contributed Technology that is necessary or reasonably useful for Adaptimmune to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit such Unilateral Adaptimmune Cells Product in the Field in the Territory, as such Product exists when such Product transitions from a Collaboration Product to a Unilateral Adaptimmune Product as set forth in this Agreement. For clarity, the Universal Cells Licensed IP excludes all Disputed Contributed Technology when used in relation to a Unilateral Adaptimmune Product.
- **1.109.2** With respect to any Collaboration Product, all (i) Universal Cells Background IP and (ii) Arising IP Controlled by Universal Cells, in each case of (i) and (ii), that is necessary or reasonably useful for Adaptimmune to make, have made, use, sell, offer for sale, import, export, Develop, Commercialize, and otherwise exploit such Collaboration Product.
- **1.110** "Universal Cells Program Inventions" means all inventions, discoveries, Know-How, or improvements generated pursuant to Universal Cells' conduct of the Universal Cells Program in accordance with this Agreement. Universal Cells Program Inventions excludes Collaboration Inventions.
- **1.111 "Universal Cells Program Product"** means a Product Directed To a Universal Cells Program Target.
- **1.112 "Universal Cells Program Target"** means a Target nominated and designated as such in accordance with Article 3 (Pre-Designation Research Program).
- **1.113** "Universal Cells Technology" means (a) Gene Editing Technology, (b) HLA Engineering Technology, (c) [\*\*\*].
- **1.114 "Universal Cells Technology Inventions"** means Collaboration Inventions that relate solely to the Universal Cells Technology, whether generated solely by or on behalf of Universal Cells or Adaptimmune or jointly by the Parties.
- **1.115** "Valid Claim" means a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.
- **1.116 Additional Definitions.** Each of the following definitions is set forth in the section of this Agreement indicated below:

TERM	Location
Acquired Party	10.3
Acquiring Party	10.3
Adaptimmune	Preamble
Adaptimmune Acquiree	17.2.2(b)
Adaptimmune Acquisition	17.2.2(b)
Adaptimmune Background Patents	9.8.1
Adaptimmune Election Period	9.2.1
Adaptimmune Impediment	9.2.2
Adaptimmune Indemnified Parties	16.2
Adaptimmune Opt-In	6.3
Additional Collaboration Target Right	3.4
Agreement	Preamble
Alliance Manager	2.1
Arising Core Adaptimmune Patents	9.8.3
Arising Core Universal Cells Patents	9.8.4
Astellas	Preamble
Audited Party	11.6
Base Product	1.69
[***]	1.113
Burdened Technology	3.3.3(a)
Burdened Technology Clearance	3.3.3(b)
Burdened Technology Limitations	3.3.3(a)
Ceasing Party	13.5.3
Co-Commercialization Budget	6.2
Co-Development Budget	5.1
Collaboration Joint Patent Rights	9.8.5
Collaboration Profit-Share Target	4.10.2
Collaboration Research Plan Budget	4.1
Collaboration Research Program Opt-Out Notice	4.11
Collaboration Substitution Target	4.6.1
Combination Product	1.69
Co-Medical Affairs Plan	2.5.2(a)
Commercialization Agreement	6.3
Competitive Activities	10.3
Continuing Development and Commercialization Notice	4.10.1
Continuing Party	13.5.3
Contributed Technology	3.5
Contributed Technology Dispute Notice	3.5

TERM	Location
Contributed Technology Notice	3.5
Defending Party	9.10.1
Disputed Contributed Technology	3.5
Early Continuation Notice	4.11
Effective Date	Preamble
Elected Unilateral Adaptimmune Product License	9.2.1
Elected Unilateral Adaptimmune Target	9.2.1
Elected Universal Cells Program Product License	9.2.2
Elected Universal Cells Program Target	9.2.2
Enforcing Party	9.9.7
Excluded Target Clearance	3.3.1
Executive Resolution Matters	2.2.4(b)
Existing Agreement	Preamble
First Collaboration Target Nomination Date	3.2.1
Indemnitee	16.3
Indemnitor	16.3
Indirect Taxes	11.9.2
JCC	2.7.1
JDC	2.4.1
JFC	2.6.1
JMAC	2.5.1
JRC	2.3.1
JSC	2.2.1
Lapsed Target	4.10.4
Licensed Unilateral Universal Cells Product Patent	1.104
Losses	16.1
Non-Excluded Target	1.44
Non-Publishing Party	12.6.3
Opt-Out Notice	5.3
Other Component	1.69
Parties	Preamble
Party	Preamble
Phase 1 Data Availability Date	4.10.1
Phase 1 Success Criteria	4.1
Publishing Party	12.6.3
Qualifying Adaptimmune Change of Control	17.2.3
Qualifying Adaptimmune CoC Notice	17.2.3(a)
Royalty Conversion Payments	17.2.3(f)

TERM	Location
Rules	14.2.1
Sale Transaction	17.2.1
Second Collaboration Target Nomination Date	3.2.1
Selling Party	1.69
Target Substitution Right	4.6.1
Term	13.1
Third Collaboration Target Nomination Date	3.2.1
Third Party Acquirer	17.2.2(a)
Third Party Claim	16.1
Third Party License	11.4.6(b)
Unilateral Adaptimmune Product Elected License Notice	9.2.1
Unilateral Adaptimmune Product-Specific Collaboration Joint Patent Rights	9.9.5(d)
Unilateral Adaptimmune Product-Specific Patents	9.8.6
Unilateral Adaptimmune Target	4.10.3(b)
Unilateral Universal Cells Product-Specific Patents	9.8.7
Universal Cells	Preamble
Universal Cells Acquiree	17.2.2(a)
Universal Cells Acquisition	17.2.2(a)
Universal Cells Background Patents	9.8.2
Universal Cells Election Period	9.2.1
Universal Cells Impediment	3.5
Universal Cells Indemnified Parties	16.1
Universal Cells Program	8.2
Universal Cells Program Product Elected License Notice	9.2.2
Universal Cells Research Activities	8.1
Universal Cells Substitution Target	4.6.1
Withholding Party	11.9.1

# **ARTICLE 2**

# **GOVERNANCE**

**2.1 Alliance Managers**. Each of the Parties will appoint a single individual to manage the activities of the Parties under the Collaboration (each, an "**Alliance Manager**") no later than thirty (30) days after the Effective Date. The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under the Collaboration. The Alliance Managers will attend all JSC meetings and the Alliance Managers or their respective designees will attend all meetings of the subcommittees (e.g. JRC, JDC, JCC, JMAC, and the JFC), and will support the co-chairpersons of the JSC and each subcommittee in the discharge of his or her responsibilities. Alliance Managers will be non-voting participants in all JSC and

subcommittee meetings, but an Alliance Manager may bring any matter to the attention of the JSC or any subcommittee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (a) be the point of first referral in all matters of conflict resolution; (b) provide a single point of communication for seeking consensus between the Parties regarding key strategy and plan issues; (c) identify and bring disputes to the attention of the JSC in a timely manner; (d) plan and coordinate cooperative efforts and internal and external communications; and (e) take responsibility for ensuring that governance activities, such as the conduct of required JSC and subcommittee meetings and production of meeting minutes, occur as set forth in this Agreement, and that the relevant action items resulting from such meetings are appropriately carried out or otherwise addressed. For clarity, an Alliance Manager has no decision making authority with respect to any activities of the Parties under the Collaboration.

# 2.2 Joint Steering Committee.

- **2.2.1 Formation and Composition**. Universal Cells and Adaptimmune hereby establish a joint steering committee ("JSC") comprised of three (3) representatives of Universal Cells or its Affiliates and three (3) representatives of Adaptimmune or its Affiliates, which such initial JSC representatives are listed on <u>Schedule 2.2.1</u> to this Agreement. The JSC will be led by two (2) co-chairs, one (1) of which shall be appointed by each Party. Each Party may change any one or more of its representatives to the JSC at any time upon written notice to the other Party. The Parties may mutually agree in writing to change the number of their representatives on the JSC, *provided* that the number of representatives from each Party shall always be equal.
- **2.2.2 Functions and Powers of JSC**. The JSC shall monitor and provide strategic oversight for the activities to be conducted under the Collaboration, and making decisions (solely as specified herein) regarding the Parties' conduct of the Collaboration pursuant to this Agreement. Without limiting the foregoing, the JSC shall:
  - (a) oversee and monitor the activities of the Parties under this Agreement;
- (b) oversee and monitor the implementation of each Collaboration Research Program in coordination with the JRC, JDC, JCC, JMAC, or JFC, and any other subcommittees the JSC may elect to form as applicable;
- (c) review and approve, each Collaboration Research Plan, Co-Development Plan, Co-Medical Affairs Plan, and Co-Commercialization Plan (including each Collaboration Research Budget, Co-Development Budget, and Co-Commercialization Budget under each such plan), and all material updates and amendments thereto;

- (d) review and discuss reports from the JRC, JDC, JCC, and JMAC and provide guidance on further Development, Manufacturing, Medical Affairs Activities, and Commercialization activities based on such reports;
- (e) approve and designate as a Collaboration Target each Target so nominated by the JRC (including each Collaboration Substitution Target) within [\*\*\*] of the nomination such Target;
- (f) review and approve any Burdened Technology Limitations with respect any Target nominated to be designated as a Collaboration Target;
- (g) approve approaches for, and monitor, Manufacturing activities conducted with respect to the Collaboration Products;
- (h) approve clinical study plans and protocols created by the JDC or JMAC for the Collaboration Products;
- (i) form any subcommittees or working groups necessary for progressing the Collaboration and achieving the objectives of this Agreement;
- (j) establish goals and strategies for the Collaboration Products, including regulatory and other Development and Commercialization strategies
- (k) resolve disputes as to matters within the decision-making authority of the JRC, JDC, JFC, JCC, JMAC and other subcommittees and working groups submitted to it in accordance with this Agreement; and
- (l) perform any and all other tasks and responsibilities that are expressly allocated to the JSC under this Agreement.
- **2.2.3 Meetings of the JSC**. The JSC shall meet at least once per Calendar Quarter or more or less often as otherwise agreed by the Parties, with the location of such meetings (which may be by videoconference or telephonically) alternating between locations designated by Adaptimmune and locations designated by Universal Cells. The chairpersons of the JSC shall be responsible for calling meetings on reasonable prior notice. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information with respect to such proposed items reasonably in advance of the applicable meeting. In addition, each Party may, at its discretion, invite to attend meetings of the JSC non-voting employees, and, with the consent of the other Party, consultants or scientific advisors, in each case, so long as such persons are bound by restrictions on use and disclosure consistent with those contained in Article 12 (Confidentiality). Each Party shall be responsible for its own costs and expenses incurred in connection with attendance by its personnel at any meeting of the JSC.

# 2.2.4 Decision Making.

(a) **General Authority**. To make any decision required of it hereunder, the JSC must have present (in person, by videoconference, or telephonically) at least one (1) representative appointed by each Party. Decisions of the JSC shall be by consensus, with each

- (b) **Escalation**. If a dispute arises that cannot be resolved by the applicable committee, subcommittee, or working group, then the Alliance Manager of either Party may cause such dispute to be referred to the JSC for resolution. Upon receipt from the JRC, JDC, JFC, JCC, JMAC, subcommittee, or working group of an unresolved matter, a meeting of the JSC shall be convened as soon as practicable in order to consider and resolve such unresolved matter. Any determination by the JSC within its scope of authority under this Agreement shall be final and binding upon the Parties. If the JSC cannot reach consensus on a matter referred to it for resolution (whether the matter originated at the JSC or the JRC, JDC, JCC, JMAC, or other subcommittee or working group) or over which it has jurisdiction, then solely with respect to [\*\*\*], such matter shall be referred to the Executive Officers for resolution in accordance with Section 14.1 (Referral of Unresolved Matters to Executive Officers) (the "Executive Resolution Matters"). Neither Party will have final decision making rights with respect to Executive Resolution Matters.
- (c) **Final Decision-Making Authority**. Except for the Executive Resolution Matters, and subject to Section 2.2.4(d) (Limitations on Final Decision-Making Authority), [\*\*\*] shall have final decision-making authority with respect to all other matters within the jurisdiction of the JSC.
- (d) **Limitations on Final Decision-Making Authority**. Notwithstanding anything to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Universal Cells (in the exercise of its final decision-making authority), the JSC, nor a Party's Executive Officers, in each case, may make a decision that could reasonably be expected to (A) require the other Party to take any action that such other Party reasonably believes would require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party entered into by such other Party (including any Third Party License) or (B) result in the other Party being required to materially increase the planned resources allocated to, or otherwise incur an unreimbursed expenditure related to, performance of activities under the Collaboration Research Program (e.g., an increase of [\*\*\*] or greater of planned resource allocation over a [\*\*\*] period).
- **2.2.5 Limitations on Authority**. The JSC shall not have any power or authority over Universal Cells' conduct of a Universal Cells Program or a Party's Development, Medical Affairs Activities, Manufacturing, or Commercialization of a Unilateral Product pursuant to this Agreement.

### 2.3 Joint Research Committee.

**2.3.1 Formation and Composition**. Universal Cells and Adaptimmune hereby establish a joint research committee ("JRC") comprised of three (3) representatives of Universal Cells or its Affiliates and three (3) representatives of Adaptimmune, which such initial JRC representatives are listed on <u>Schedule 2.3.1</u> to this Agreement. The JRC will be led by two (2) co-chairs, one (1) of which shall be appointed by each Party. Each Party may change any one or more of its representatives to the JRC at any time upon written notice to the other Party. The

Parties may mutually agree to change the number of their representatives on the JRC, *provided* that the number of representatives from each Party shall always be equal.

- **2.3.2 Functions and Powers of JRC**. The JRC shall have overall responsibility for reviewing, overseeing, and serving as a forum for information exchange, and making decisions (solely as specified herein) regarding the Parties' conduct of the nonclinical and pre-clinical Development activities under the Collaboration Research Programs pursuant to this Agreement. Without limiting the foregoing, the JRC shall:
  - (a) oversee the implementation of the Collaboration Research Programs;
- (b) generate and submit to the JSC for approval each Collaboration Research Plan, and all updates and amendments thereto;
- (c) make recommendations to the JSC regarding approval of the initial nomination of Targets for designation as Collaboration Targets (including Collaboration Substitution Targets, in consultation with the JDC);
- (d) oversee all activities under each Collaboration Research Plan to identify and Develop the Collaboration Products, including all nonclinical and pre-clinical studies under each Collaboration Research Plan:
- (e) develop plans and strategies to be included in each Collaboration Research Plan for Manufacturing of Collaboration Products for use in the performance of activities under such plans; and
- (f) perform any and all tasks and responsibilities that are expressly attributed to the JRC under this Agreement.
- **2.3.3 Meetings of the JRC**. The JRC shall meet at least once per month or more or less often as otherwise agreed by the Parties until the initial designation of the three (3) Collaboration Targets in accordance with Article 3 (Pre-Designation Research Program). Thereafter, the JRC will meet only on an as needed basis (*e.g.*, in order to nominate a fourth (4th) Collaboration Target in connection with exercising its Additional Collaboration Target Right or to evaluate a Collaboration Substitution Target). The location of such meetings (which may be inperson or by videoconference or telephonically) will alternate between locations designated by Adaptimmune and locations designated by Universal Cells. The chairpersons of the JRC shall be responsible for calling meetings on reasonable prior notice. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information with respect to such proposed items reasonably in advance of the applicable meeting. In addition, each Party may, at its discretion, invite to attend meetings of the JRC non-voting employees, and, with the consent of the other Party, consultants or scientific advisors, in each case, so long as such persons are bound by restrictions on use and disclosure consistent with those contained in Article 12 (Confidentiality). Each Party shall be responsible for its own costs and expenses incurred in connection with attendance by its personnel at any meeting of the JRC.

- **2.3.4 Decision Making.** To make any decision required of it hereunder, the JRC must have present (in person, by videoconference or telephonically) at least one (1) representative appointed by each Party. Decisions of the JRC shall be by consensus, with each Party's representatives having one (1) vote irrespective of the number of representatives of such Party in attendance. If the JRC cannot reach consensus or a dispute arises that cannot be resolved within the JRC (e.g., regarding the nomination of a Collaboration Target or Collaboration Substitution Target), then such matter shall be escalated to the JSC for prompt resolution.
- **2.3.5 Limitations**. The JRC shall not have the power to make decisions that conflict with, amend, interpret, modify, or waive compliance with this Agreement. The JRC shall not have any power or authority over Universal Cell's conduct of a Universal Cells Program or a Party's Development, Medical Affairs Activities, Manufacturing, or Commercialization of a Unilateral Product pursuant to this Agreement.

### 2.4 Joint Development Committee.

- **2.4.1 Formation and Composition.** Universal Cells and Adaptimmune shall, at least one (1) year prior to the anticipated first submission of an IND for the first Collaboration Product, establish a joint development committee ("**JDC**") comprised of three (3) representatives of Universal Cells or its Affiliates and three (3) representatives of Adaptimmune. The JDC will be led by two (2) co-chairs, one (1) of which shall be appointed by each Party. Each Party may change any one or more of its representatives to the JDC at any time upon written notice to the other Party. The Parties may mutually agree in writing to change the number of their representatives on the JDC, *provided* that the number of representatives from each Party shall always be equal.
- **2.4.2 Functions and Powers of JDC**. The JDC shall have overall responsibility for reviewing, overseeing, and serving as a forum for information exchange and making decisions (solely as specified herein) regarding the Parties' conduct of clinical Development activities under each Collaboration Research Program for each Collaboration Target and all Development activities under each Co-Development Program for each Collaboration Profit-Share Target pursuant to this Agreement. Without limiting the foregoing, the JDC shall:
- (a) discuss, prepare, and approve for submission to the JSC for approval the Co-Development Plan for each Collaboration Profit-Share Product, including each Co-Development Budget, and all material updates and amendments thereto;
- (b) create, implement, and review the overall strategy for global Development and the design of all clinical trials and nonclinical and pre-clinical studies to be conducted under each Collaboration Research Plan and Co-Development Plan;
- (c) decide whether and when to initiate or discontinue any clinical trial or nonclinical or pre-clinical study under each Collaboration Research Program or Co-Development Program, in each case, in a manner that enables each Party to comply with Applicable Law and manage subject safety;
- (d) allocate budgeted resources and determine priorities for each clinical trial under each Collaboration Research Plan and Co-Development Plan;

- (e) oversee the conduct of Development activities to be conducted jointly by the Parties under this Agreement for Collaboration Products (including Collaboration Profit-Share Products), including all clinical trials under each Collaboration Research Plan and Co-Development Plan;
- (f) discuss the requirements for obtaining Regulatory Approval of Collaboration Products in the Territory and approve the regulatory strategy (for inclusion in the applicable Co-Development Plan) with respect to the Collaboration Profit-Share Products;
- (g) prepare all MAAs for each Collaboration Profit-Share Product and review and discuss all filings, submissions to, and correspondence with Regulatory Authorities regarding any Regulatory Approval for any Collaboration Profit-Share Product;
- (h) in consultation with the JMAC, develop, approve and implement the publication strategy for Collaboration Products, including scientific presentations (for inclusion in the Research Collaboration Plan and Co-Development Plan) in compliance with [\*\*\*] current publication policy, which is set forth in the publications policy attached as <u>Schedule 2.4.2</u>;
- (i) make recommendations in coordination with the JRC regarding the nomination of Targets as Collaboration Substitution Targets (but not the initial nomination of Targets for designation as Collaboration Targets) for approval by the JSC;
- (j) develop plans and strategies to be included in each Co-Development Plan for Manufacturing of Collaboration Profit-Share Products for clinical Development purposes;
- (k) prepare periodic reports on the Parties' clinical Development activities with respect to Collaboration Products for submission to the JSC; and
- (l) perform any and all tasks and responsibilities that are expressly attributed to the JDC under this Agreement.
- **2.4.3 Meetings of the JDC**. The JDC shall meet at least once per Calendar Quarter or more or less often as otherwise agreed by the Parties. The location of such meetings (which may be in person or by videoconference or telephonically) will alternate between locations designated by Adaptimmune and locations designated by Universal Cells. The chairpersons of the JDC shall be responsible for calling meetings on reasonable prior notice. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information with respect to such proposed items reasonably in advance of the applicable meeting. In addition, each Party may, at its discretion, invite to attend meetings of the JDC non-voting employees, and, with the consent of the other Party, consultants or scientific advisors, in each case, so long as such persons are bound by restrictions on use and disclosure consistent with those contained in Article 12 (Confidentiality). Each Party shall be responsible for its own costs and expenses incurred in connection with attendance by its personnel at any meeting of the JDC.
- **2.4.4 Decision Making**. To make any decision required of it hereunder, the **JDC** must have present (in person, by videoconference or telephonically) at least one (1) representative appointed by each Party. Decisions of the JDC shall be by consensus, with each Party's representatives having one (1) vote irrespective of the number of representatives of such

Party in attendance. If the JDC cannot reach consensus or a dispute arises that cannot be resolved within the JDC (*e.g.*, regarding the nomination of a Target for designation as a Collaboration Substitution Target), then such matter shall be escalated to the JSC for prompt resolution.

**2.4.5 Limitations**. The JDC shall not have the power to make decisions that conflict with, amend, interpret, modify, or waive compliance with this Agreement. The JDC shall not have any power or authority over Universal Cells' conduct of a Universal Cells Program or a Party's Development, Medical Affairs Activities, Manufacturing, or Commercialization of a Unilateral Product pursuant to this Agreement.

#### 2.5 Joint Medical Affairs Committee.

- **2.5.1 Formation and Composition**. Universal Cells and Adaptimmune shall, within thirty (30) days of the first designation of a Collaboration Profit-Share Product, establish a joint medical affairs committee ("**JMAC**") comprised of three (3) representative of Universal Cells or its Affiliates and three (3) representative of Adaptimmune, each of whom has a background in medical affairs. The JMAC will be led by two (2) co-chairs, one (1) of which shall be appointed by each Party. Each Party may change any one or more of its representatives to the JMAC at any time upon written notice to the other Party. The Parties may mutually agree in writing to change the number of their representatives on the JMAC, *provided* that the number of representatives from each Party shall always be equal.
- **2.5.2 Functions and Powers of JMAC**. The JMAC shall have overall responsibility for reviewing, overseeing, and serving as a forum for information exchange and decision making (solely as specified herein) regarding the Parties' conduct of Medical Affairs Activities for each Collaboration Profit Share Product pursuant to this Agreement. Without limiting the foregoing, the JMAC shall:
- (a) develop and submit to the JSC for approval the Co-Medical Affairs Plan within ninety (90) days after the initiation of the first Pivotal Clinical Trial for such Collaboration Profit-Share Product;
- (b) oversee the implementation of Medical Affairs Activities under each Co-Medical Affairs Plan and all updates and amendments thereto;
- (c) prepare periodic reports on the Parties' Medical Affairs activities with respect to Collaboration Profit-Share Products for submission to the JSC; and
- (d) perform any and all tasks and responsibilities that are expressly attributed to the JMAC under this Agreement.
- **2.5.3 Meetings of the JMAC**. The JMAC shall meet at least once per Calendar Quarter or more or less often as otherwise agreed by the Parties. The location of such meetings (which may be in person or by videoconference or telephonically) will alternate between locations designated by Adaptimmune and locations designated by Universal Cells. The chairpersons of the JMAC shall be responsible for calling meetings on reasonable prior notice. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information with respect to such proposed items reasonably in advance of the

applicable meeting. In addition, each Party may, at its discretion invite to attend meetings of the JMAC non-voting employees, and, with the consent of the other Party, consultants or scientific advisors, in each case, so long as such persons are bound by restrictions on use and disclosure consistent with those contained in Article 12 (Confidentiality). Each Party shall be responsible for its own expenses incurred in connection with attendance by its personnel at any meeting of the JMAC.

- **2.5.4 Decision Making.** To make any decision required of it hereunder, the JMAC must have present (in person, by videoconference or telephonically) at least one (1) representative appointed by each Party. Decisions of the JMAC shall be by consensus, with each Party's representatives having one (1) vote irrespective of the number of representatives of such Party in attendance. If the JMAC cannot reach consensus or a dispute arises that cannot be resolved within the JMAC, then such matter shall be escalated to the JSC for prompt resolution.
- **2.5.5 Limitations**. The JMAC shall not have the power to make decisions that conflict with, amend, interpret, modify, or waive compliance with this Agreement. The JMAC shall not have any power or authority over Universal Cells' conduct of a Universal Cells Program or a Party's Development, Medical Affairs Activities, Manufacturing, or Commercialization of a Unilateral Product pursuant to this Agreement.

#### **2.6 Joint Finance Committee.**

- **2.6.1 Formation and Composition**. Universal Cells and Adaptimmune shall, within thirty (30) days of the first nomination of a Collaboration Target, establish a joint finance committee ("**JFC**") comprised of one (1) representative of Universal Cells or its Affiliates and one (1) representative of Adaptimmune, each of whom has a background in finance. The JFC will be led by two (2) co-chairs, one (1) of which shall be appointed by each Party. Each Party may change any one or more of its representatives to the JFC at any time upon written notice to the other Party.
- **2.6.2 Functions and Powers of JFC**. The JFC shall have overall responsibility for providing input and support to the JRC, JDC, JCC, JMAC, and JSC with respect to accounting and financial matters relating to the conduct of the Collaboration. Without limiting the foregoing, the JFC shall:
- (a) advise the JRC with respect to establishing each Collaboration Research Budget for the applicable Collaboration Research Plan and advise the JSC with respect to approval of the same;
- (b) advise the JDC and JCC with respect to setting the Co-Development Budget and the Co-Commercialization Budgets for the Co-Development Plan and Co-Commercialization Plan (respectively) and advise the JSC with respect to approval of the same;
- (c) recommend to the JSC methods for calculating Profit in accordance with <u>Schedule</u> <u>11.3;</u>
- (d) reconciling the Parties' reports of Development Costs, Program Costs, Net Sales, Sublicensing Revenues, and recoveries pursuant to Section 9.9 (Patent

Enforcement) and issuing a reconciliation report calculating Profit and total Development Costs and allocating each Party's interest therein in accordance with <u>Schedule 11.3</u>;

- (e) ensure consistency of reporting between the Parties of all costs and expenses under the Collaboration;
- (f) resolve any disputes regarding costs and expenses and the allocation thereof under the Collaboration: and
- (g) perform any and all tasks and responsibilities that are expressly attributed to the JFC under this Agreement.
- **2.6.3 Meetings of the JFC**. The JFC shall meet at least once per Calendar Quarter or more or less often as otherwise agreed by the Parties. The location of such meetings (which may be in person or by videoconference or telephonically) will alternate between locations designated by Adaptimmune and locations designated by Universal Cells. The chairpersons of the JFC shall be responsible for calling meetings on reasonable prior notice. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information with respect to such proposed items reasonably in advance of the applicable meeting. In addition, each Party may, at its discretion invite to attend meetings of the JFC non-voting employees, and, with the consent of the other Party, consultants or scientific advisors, in each case, so long as such persons are bound by restrictions on use and disclosure consistent with those contained in Article 12 (Confidentiality). Each Party shall be responsible for its own expenses incurred in connection with attendance by its personnel at any meeting of the JFC.
- **2.6.4 Decision Making**. To make any decision required of it hereunder, the **JF**C must have present (in person, by videoconference or telephonically) at least one (1) representative appointed by each Party. Decisions of the JFC shall be by consensus, with each Party's representatives having one (1) vote irrespective of the number of representatives of such Party in attendance. If the JFC cannot reach consensus or a dispute arises that cannot be resolved within the JFC, then such matter shall be escalated to the JSC for prompt resolution.
- **2.6.5 Limitations**. The JFC shall not have the power to make decisions that conflict with, amend, interpret, modify, or waive compliance with this Agreement. The JFC shall not have any power or authority over Universal Cells' conduct of a Universal Cells Program or a Party's Development, Medical Affairs Activities, Manufacturing, or Commercialization of a Unilateral Product pursuant to this Agreement.

#### 2.7 Joint Commercialization Committee.

**2.7.1 Formation and Composition**. Universal Cells and Adaptimmune shall, within thirty (30) days of the first designation of a Collaboration Profit-Share Product, establish a joint commercialization committee ("**JCC**") comprised of three (3) representatives of Universal Cells or its Affiliates and three (3) representatives of Adaptimmune. The JCC will be led by two (2) co-chairs, one (1) of which shall be appointed by each Party. Each Party may change any one or more of its representatives to the JDC at any time upon written notice to the other Party. The Parties may mutually agree in writing to change the number of their representatives on the JCC, *provided* that the number of representatives from each Party shall always be equal.

- **2.7.2 Functions and Powers of JCC**. The JCC shall have overall responsibility for reviewing, overseeing, and serving as a forum for information exchange and making decisions (solely as specified herein) regarding the Parties' conduct of each Co-Commercialization Program for each Collaboration Profit-Share Product pursuant to this Agreement. Without limiting the foregoing, the JCC shall:
- (a) discuss, prepare, and approve for submission to the JSC for approval the Co-Commercialization Plan for each Collaboration Profit-Share Product, including each Co-Commercialization Budget and all material updates and amendments thereto;
- (b) oversee the implementation of Commercialization activities to be conducted jointly by the Parties under each Co-Commercialization Plan;
- (c) develop plans and strategies to be included in each Co-Commercialization Plan for Manufacturing of Collaboration Profit-Share Products for Commercial purposes;
- (d) prepare periodic reports on the Parties' Commercialization activities with respect to Collaboration Profit-Share Products for submission to the JSC; and
- (e) perform any and all tasks and responsibilities that are expressly attributed to the JCC under this Agreement.
- **2.7.3 Meetings of the JCC**. The JCC shall meet at least once per Calendar Quarter or more or less often as otherwise agreed by the Parties. The location of such meetings (which may be in person or by videoconference or telephonically) will alternate between locations designated by Adaptimmune and locations designated by Universal Cells. The chairpersons of the JCC shall be responsible for calling meetings on reasonable prior notice. Each Party shall use reasonable efforts to make all proposals for agenda items and to provide all appropriate information with respect to such proposed items reasonably in advance of the applicable meeting. In addition, each Party may, at its discretion, invite to attend meetings of the JCC non-voting employees, and, with the consent of the other Party, consultants or scientific advisors, in each case, so long as such persons are bound by restrictions on use and disclosure consistent with those contained in Article 12 (Confidentiality). Each Party shall be responsible for its own expenses incurred in connection with attendance by its personnel at any meeting of the JCC.
- **2.7.4 Decision Making.** In order to make any decision required of it hereunder, the JCC must have present (in person, by videoconference or telephonically) at least one (1) representative appointed by each Party. Decisions of the JCC shall be by consensus, with each Party's representatives having one (1) vote irrespective of the number of representatives of such Party in attendance. If the JCC cannot reach consensus or a dispute arises that cannot be resolved within the JCC, then such matter shall be escalated to the JSC for prompt resolution.
- **2.7.5 Limitations**. The JCC shall not have the power to make decisions that conflict with, amend, interpret, modify, or waive compliance with this Agreement. The JCC shall not have any power or authority over Universal Cells' conduct of a Universal Cells Program or a Party's Development, Medical Affairs Activities, Manufacturing, or Commercialization of a Unilateral Product pursuant to this Agreement.

#### **ARTICLE 3**

#### PRE-DESIGNATION RESEARCH PROGRAM

**3.1 Identification And Validation Of Targets**. From the Effective Date and continuing from time to time thereafter until the Target Identification and Tracking End Date, the Parties shall use Commercially Reasonable Efforts to identify and nominate Targets as set forth in this Article 3 (Pre-Designation Research Program) based on data and results that are in the public domain or that have been generated prior to the Effective Date. Each Party shall provide any information relevant to Targets being discussed and shall collaborate to assess and identify Targets suitable for nomination as Collaboration Targets, but in no event shall Adaptimmune be required to perform any additional activities to validate any Target nominated for designation as a Collaboration Target or a Universal Cells Program Target, in each case, that are not set forth in a Collaboration Research Plan. Each Party shall be responsible for its own costs and expenses in connection with activities under this Section 3.1 (Identification and Validation of Targets), but not activities under any Collaboration Research Plan, the allocation between the Parties for costs and expenses thereunder is set forth in Section 4.5 (Collaboration Research Program Costs).

### 3.2 Nomination.

- **3.2.1** Collaboration Targets. The JRC shall nominate and submit to the JSC for approval (a) the first (1<sup>st</sup>) Target to be nominated for designation as a Collaboration Target within [\*\*\*] after the Effective Date (the "First Collaboration Target Nomination Date"), (b) the second (2<sup>nd</sup>) Target to be nominated for designation as a Collaboration Target within [\*\*\*] after the First Collaboration Target Nomination Date (the "Second Collaboration Target Nomination Date"), and (c) the third (3<sup>rd</sup>) Target to be nominated for designation as a Collaboration Target within [\*\*\*] after the Second Collaboration Target Nomination Date (the "Third Collaboration Target Nomination Date").
- **3.2.2 Universal Cells Program Targets**. Commencing on the Effective Date and continuing until the [\*\*\*] anniversary thereafter, Universal Cells shall have the right to nominate, by providing written notice to the JRC, Targets for designation as Universal Cells Program Targets.
- **3.2.3 Target Maximums**. A maximum of three (3) distinct Targets shall be nominated for designation, or so designated, as Collaboration Targets under this Agreement ([\*\*\*]). A maximum of two (2) distinct Universal Cells Program Targets may be nominated for designation at a given time, or so designated, as Universal Cells Program Targets.
- **3.2.4 Nomination Exclusivity.** Once a Target is nominated for designation as a Collaboration Target, it cannot also be nominated for designation as a Universal Cells Program Target, and once a Target is nominated for designation as a Universal Cells Program Target, it cannot also be nominated for designation as a Collaboration Target. Upon nomination of a Target and until such Target is designated or finally determined to be either an Excluded Target or a Target for which Burdened Technology Clearance is obtained in accordance with Section 3.3 (Designation of Nominated Targets), Adaptimmune shall not, itself or with or through an Affiliate or a Third Party, commence any Development activities it is not conducting at the time of

nomination with respect to Cell products specific to such Target, or grant any Third Party any rights to conduct such activities, except to the extent necessary to evaluate such Target for designation as a Collaboration Target or Universal Cells Program Target, as applicable, unless and until such Target is determined to be an Excluded Target or is designated as a Collaboration Target or Universal Cells Program Target (in which case such activities would be permitted within the scope of this Agreement).

- 3.3 Designation of Nominated Targets. Upon written notice provided to the JRC of the nomination of a Target for designation as a Collaboration Target or a Universal Cells Program Target as set forth above, the JRC shall first determine within [\*\*\*] days of the nomination thereof whether such Target is an Excluded Target, and if so, whether such Target should receive Excluded Target Clearance as set forth in Section 3.3.1 (Excluded Targets). If the JRC determines that such Target is not an Excluded Target, or if the JRC determines such Target is an Excluded Target but receives Excluded Target Clearance for such Target, then within [\*\*\*] days after such determination is made or such Excluded Target Clearance is received, the Parties shall determine whether Burdened Technology Limitations applicable to such Target and Products Directed to such Target exist pursuant to Section 3.3.2 (Acceptance of Burdened Technology), and if so, whether the JSC will provide Burdened Technology Clearance as set forth in Section 3.3.3(b) (Notice Obligations). If no Burdened Technology Limitations apply to such Target, or such Target receives Burdened Technology Clearance, then such nominated Target shall be designated as a Collaboration Target or Universal Cells Program Target (as applicable). A decision as to whether any nominated Target will be designated as a Collaboration Target or a Universal Cells Program Target shall be made within [\*\*\*] of the nomination of such Target.
- **3.3.1 Excluded Targets.** Adaptimmune shall maintain a complete list of Targets that are Excluded Targets from the Effective Date until the Target Identification and Tracking End Date, with such list including the date on which each listed Target becomes an Excluded Target. The Excluded Target list shall be made available in the event of a dispute under Section 3.3.6 (Dispute as to Excluded Targets) to the mutually acceptable Expert, who shall not disclose the content of such list to Universal Cells except for information on the list specifically regarding the disputed Target. Adaptimmune shall notify the JRC whether a nominated Target is an Excluded Target within [\*\*\*] after such Target is nominated. Any notice from Adaptimmune stating that a nominated Target is an Excluded Target shall include information regarding the basis upon which such nominated Target is an Excluded Target (e.g., because such Target is the subject of an Active Research Program or a Third Party License or term sheet negotiations therefor), and a statement as to whether Adaptimmune is willing nevertheless to allow such Excluded Target to be designated as a Collaboration Target or a Universal Cells Program Target, as applicable ("Excluded Target Clearance"). If Adaptimmune notifies the JRC that such Target is not an Excluded Target, or if Adaptimmune notifies the JRC that such Target is an Excluded Target but nevertheless provides Excluded Target Clearance, then such nominated Target shall remain eligible for designation as a Collaboration Target or Universal Cells Program Target (as applicable) unless Burdened Technology Limitations apply and no Burdened Technology Clearance is obtained as set forth in Section 3.3.3(b) (Notice Obligations). However, if Adaptimmune notifies the JRC that the nominated Target is an Excluded Target, and Adaptimmune does not provide an Excluded Target Clearance within [\*\*\*] days of notification of nomination of such Target for designation, then such Target may not be designated as a Collaboration Target or a Universal Cells Program Target (as applicable) and in lieu of such previously nominated Excluded Target, the JRC

(with respect to the nomination of a Target for designation as a Collaboration Target) or Universal Cells (with respect to the nomination of a Target for designation as a Universal Cells Program Target) may nominate an alternative Target for designation as a Collaboration Target or Universal Cells Program Target (as applicable) as described in this Section 3.3 (Designation of Nominated Targets).

**3.3.2 Acceptance of Burdened Technology**. If Adaptimmune does not provide written notice to the JSC (with respect to a Target nominated for designation as a Collaboration Target) or to Universal Cells (with respect to a Target nominated for designation as a Universal Cells Program Target) that such nominated Target is an Excluded Target, or if Adaptimmune provides Excluded Target Clearance notwithstanding the fact that such Target is an Excluded Target, then such Target shall become so designated as a Collaboration Target or Universal Cells Program Target (as applicable) once the JSC (as to a proposed Collaboration Target) or Universal Cells (as to a proposed Universal Cells Program Target) accepts any Burdened Technology Limitations with respect to such Target as set forth in Section 3.3.3 (Burdened Technology Limitations) below.

# 3.3.3 Burdened Technology Limitations.

- (a) **Burdened Technology Limitations**. The Parties acknowledge that certain materials and data and information relating thereto Controlled by a Party and included in the Adaptimmune Technology or the Universal Cells Technology may include financial or other obligations to Third Parties ("**Burdened Technology**"). Accordingly, the use of such Burdened Technology in a Collaboration Research Program, Collaboration Profit-Share Program or Universal Cells Program (as applicable), or the Development, Manufacture, Medical Affairs Activities, or Commercialization of products resulting from the use of such Burdened Technology, may result in (i) financial or obligations to Third Parties relating to the practice of such Burdened Technology, (ii) limitations on the use of certain information contained in the Burdened Technology, or (iii) a reduction in the rights of the Parties under this Agreement under the Burdened Technology relative to their rights under other technology licensed to such Party pursuant to this Agreement (the obligations and limitations set forth in the foregoing clauses ((i) through (iii)), the "**Burdened Technology Limitations**").
- (b) **Notice Obligations**. Each Party will inform the other Party of any Burdened Technology Limitations relating to any Adaptimmune Technology or Universal Cells Technology that it may Control in relation to any Target nominated for designation as a Collaboration Target or Universal Cells Program Target no later than [\*\*\*] after it is determined pursuant to Section 3.3.1 (Excluded Targets) whether such Target remains eligible for such designation. Such Target will be designated as a Collaboration Target or Universal Cells Program Target (as applicable) if, after evaluation of the nature and scope of the Burdened Technology Limitations, the JSC (with respect to a Target nominated for designation as a Collaboration Target) or Universal Cells (with respect to a Target nominated for designation as a Universal Cells Program Target) approves such Burdened Technology Limitations ("Burdened Technology Clearance").
- (c) If no Burdened Technology Limitations apply to a nominated Target, then such Target will be designated, effective as of the expiration of the [\*\*\*] time period in

Section 3.3.3(b) (Notice Obligations), as a Collaboration Target or a Universal Cells Program Product, as application. If Burdened Technology Limitations apply, but no Burdened Technology Clearance is obtained within such [\*\*\*] day time period, then the JRC (with respect to the nomination of a Target for designation as a Collaboration Target) or Universal Cells (with respect to the nomination of a Target for designation as a Universal Cells Program Target) may nominate an alternative Target for designation as a Collaboration Target or Universal Cells Program Target (as applicable) as described in this Section 3.3 (Designation of Nominated Targets).

- **3.3.4 Target Maximums.** A maximum of three (3) distinct Collaboration Targets may be designated ([\*\*\*]). A maximum of two distinct (2) Universal Cells Program Targets may be designated.
- **3.3.5 Designation Exclusivity**. Once a Target is designated as a Collaboration Target, it cannot also be designated as a Universal Cells Program Target, and once a Target is designated as a Universal Cells Program Target, it cannot also be designated as a Collaboration Target.
- **3.3.6 Dispute as to Excluded Targets.** If Universal Cells' members of the JSC disagree with, or otherwise question, Adaptimmune's notice that a Target nominated for designation as a Collaboration Target or Universal Cells Program Target under this Section 3.3 (Designation of Nominated Targets) is an Excluded Target, then such members may request that, subject to any confidentiality obligations to any Third Parties, Adaptimmune provide further information to support its position that the nominated Target is an Excluded Target. If, within [\*\*\*] after the JSC's receipt of such further information, Universal Cells' members of the JSC still disagree or question in good faith whether such Target is an Excluded Target, then the Parties shall engage a mutually acceptable Expert to determine whether the nominated Target is an Excluded Target. The Expert shall enter into confidentiality agreement with both Parties and shall render his or her decision within [\*\*\*] after being engaged after reviewing information from Adaptimmune supporting its determination that a nominated Target is an Excluded Target. Subject to any confidentiality obligations to any Third Parties, each Party shall reasonably cooperate with the Expert to provide to him or her reasonable additional information requested by the Expert to determine whether such Target is an Excluded Target. If the Expert finds that the nominated Target is an Excluded Target, then Universal Cells shall be responsible for all costs and expenses of appointing the Expert and such Target shall not become a Collaboration Target or a Universal Cells Program Target and the JRC or Universal Cells, as applicable, may nominate alternative Targets to be nominated for designation as a Collaboration Target or a Universal Cells Program Target, as applicable. If the Expert finds that the nominated Target is not an Excluded Target, then Adaptimmune shall be responsible for all costs and expenses of appointing the Expert and such Target shall become a Collaboration Target or a Universal Cells Program Target as applicable.
  - 3.4 [\*\*\*]
- **3.5 Contributed Technology.** Prior to contributing Universal Cells Background IP for use in a Collaboration Product, [\*\*\*] ("**Contributed Technology**"), Universal Cells will disclose to Adaptimmune in writing (the "**Contributed Technology Notice**") the details of such Universal Cells Background IP it proposes to use for such Collaboration Product, as well as whether an exclusive Elected Unilateral Adaptimmune Product License would be available if such

Collaboration Product were to become a Unilateral Adaptimmune Product, and if not, provide a description of any basis for it not being then available (*e.g.*, certain rights have been licensed out in a manner precluding the grant of the exclusive Elected Unilateral Adaptimmune Product License) (a "**Universal Cells Impediment**"). [\*\*\*].

### **ARTICLE 4**

### COLLABORATION RESEARCH PROGRAM

- **Collaboration Research Plans**. Within [\*\*\*] after the designation of a Collaboration Target (either 4.1 pursuant to an initial designation pursuant to Article 3 (Pre-Designation Research Program), including in the exercise of the Additional Collaboration Target Right, or a designation in connection with a Target Substitution Right conducted pursuant to Section 4.6 (Target Substitution)), the JRC, in consultation with the JDC if it then exists, shall prepare and send to the JSC for approval a Collaboration Research Plan for the Collaboration Research Program for such Collaboration Target. Each Collaboration Research Plan shall include details for the Development activities (non-clinical, pre-clinical, and clinical) to be conducted by the Parties from designation of the relevant Target until the end of the first Phase 1 Clinical Trial for a Collaboration Product Directed To such Target, including, as may be applicable, (a) characterization work in relation to such Collaboration Target, (b) any other nonclinical or pre-clinical Development activities to be conducted with respect to Collaboration Products Directed To such Collaboration Target, (c) requirements for a "successful" Phase 1 Clinical Trial for Collaboration Products Developed under such Collaboration Research Plan demonstrating that Development of such Collaboration Product should be further progressed (for each Collaboration Research Plan, the "Phase 1 Success Criteria") and other criteria agreed upon by the JDC pursuant to Section 4.2 (Collaboration Research Program Parameters), and (d) a budget for the costs and expenses of activities to be incurred in connection with the conduct of activities under the Collaboration Research Plan (the "Collaboration Research Plan Budget"). Collaboration Research Plan shall be updated from time to time as agreed by the JRC in consultation with JDC, but in any event at least once per Calendar Year.
- **4.2 Collaboration Research Program Parameters.** With respect to each Collaboration Research Program, the JRC, in consultation with the JDC, shall discuss [\*\*\*]. For each Collaboration Research Program, the JRC, in consultation with the JDC, shall adopt project progression guidelines, including lead selection for the Collaboration Products Developed under such Collaboration Research Program. Additionally, the JRC, in consultation with the JDC, shall discuss and agree on completion requirements for each stage of the Development activities to be conducted pursuant to each Collaboration Research Program for the Collaboration Products that are Developed under such Collaboration Research Program, including go/no-go criteria for advancing a Collaboration Product into a Phase 1 Clinical Trial. The JDC shall update the applicable Collaboration Research Plan accordingly with such agreed-upon criteria.
- **4.3 Conduct of Collaboration Research Program**. Each Party shall use Commercially Reasonable Efforts to conduct the activities for each Collaboration Research Program that are assigned to it under the Collaboration Research Plan for such Collaboration Research Program in accordance with the timeframes for completion of such activities set forth in such plan. The Parties acknowledge and agree that neither Party guarantees the success of tasks

undertaken under a Collaboration Research Program. The Parties intend that they will Develop one Collaboration Product for each Collaboration Target; provided that the Parties may agree to modify and improve such Collaboration Product in connection with the Development thereof.

- Conduct of Phase 1 Clinical Trial for Collaboration Product. Unless the JSC agrees otherwise, [\*\*\*] shall lead the conduct of and shall be the sponsor for any Phase 1 Clinical Trial for a Collaboration Product pursuant to a Collaboration Research Program, including all related IND submissions and regulatory communications in connection therewith. Adaptimmune will provide regular updates to [\*\*\*] regarding the conduct of any such Phase 1 Clinical Trial for a Collaboration Product and, through the JDC, will review and discuss the protocol for any such Phase 1 Clinical Trial and any material amendments thereto. In addition, [\*\*\*] will provide to [\*\*\*] for review all substantive regulatory submissions and correspondence related to any such Phase 1 Clinical Trial prior to submission thereof and will consider all timely comments [\*\*\*] thereon in good faith. To the extent permitted by the applicable Regulatory Authority, one representative of [\*\*\*] may attend and participate in meetings with Regulatory Authorities in the Territory directly relating to the conduct of any Phase 1 Clinical Trial for a Collaboration Product. Upon completion of the first Phase 1 Clinical Trial conducted for a Collaboration Product led and sponsored by [\*\*\*], the JDC shall coordinate the process for transferring promptly the ownership and sponsorship of the relevant IND to [\*\*\*], with such process to be completed within [\*\*\*] after the issuance of the final study report from such Phase 1 Clinical Trial. Each Party shall have a right of reference to all regulatory submissions made for Collaboration Products to the extent relating to the Adaptimmune Technology (for Adaptimmune) or the Universal Cells Technology (for Universal Cells).
- Collaboration Research Program Costs. Universal Cells shall be responsible for the costs and 4.5 expenses of the conduct of all activities under each Collaboration Research Program for the Collaboration Products thereunder (regardless of whether such activities are to be conducted by Universal Cells or Adaptimmune), including Development activities such as the conduct of a Phase 1 Clinical Trial for Collaboration Products to be conducted under such Collaboration Research Program and Manufacturing activities to supply Collaboration Products for use in such Collaboration Research Program. The anticipated costs and expenses of such activities shall be set forth in the Collaboration Research Plan Budget for each Collaboration Research Plan, which budget will be updated as necessary in connection with any update to the applicable Collaboration Research Plan. If the Collaboration Research Plan is updated to require Adaptimmune to perform additional Development activities, but the JSC does not approve a corresponding increase in the Collaboration Research Budget to reflect the performance of such additional activities, then Adaptimmune will not be required to perform any additional activities in the updated Collaboration Research Plan to the extent that performance of such activities would exceed the amount budgeted for the performance of such activities in the then-current Collaboration Research Budget. If, during any Calendar Year, Adaptimmune incurs more than [\*\*\*] of the amount included in the then-current Collaboration Research Plan Budget for such Calendar Year, then unless otherwise approved by the JSC or such amounts are incurred as a result of Universal Cells' failure to perform any of its obligations under this Agreement, Universal Cells shall have no obligation to reimburse Adaptimmune for any such excess amounts. Furthermore, unless otherwise agreed by the JRC, in no event will the amount to be incurred pursuant to the Collaboration Research Plan Budget exceed in the aggregate [\*\*\*] in total on a per Collaboration Target basis for activities conducted by the Parties pursuant to the Collaboration Research Plan

during any Calendar Year, exclusive of the costs of the conduct of any Phase 1 Clinical Trial for a Collaboration Product. In accordance with a procedure to be agreed by the JRC in connection with development and approval of the Collaboration Research Plan and Collaboration Research Budget for each Collaboration Research Program, no less frequently than each Calendar Quarter, Universal Cells shall reimburse all of Adaptimmune's costs and expenses on an FTE Cost plus Out of Pocket Cost basis incurred for activities conducted pursuant to each Collaboration Research Plan to the extent consistent with this Section 4.5 (Collaboration Research Program Costs). The allocation between the Parties of costs and expenses incurred to Develop Collaboration Products beyond activities set forth in the applicable Collaboration Research Plan for the Collaboration Target that such Collaboration Products are Directed To are set forth in Article 5 (Co-Development of Collaboration Profit-Share Products).

# 4.6 Target Substitution.

4.6.1 Pre-IND Substitutions for Collaboration Targets or Universal Cells Program **Targets**. Prior to the submission of the first IND for a Collaboration Product Directed To a Collaboration Target or a Universal Cells Program Product Directed To a Universal Cells Program Target (as applicable), the JRC, in consultation with the JDC (with respect to a Collaboration Target) or Universal Cells (with respect to a Universal Cells Program Target), as applicable, may elect to nominate a substitute Target to replace such then-designated Collaboration Target or Universal Cells Program Target (as applicable) (a "Collaboration Substitution Target" with respect to a Collaboration Target or a "Universal Cells Substitution Target" with respect to a Universal Cells Program Target). In such case, Section 3.2 (Nomination) and Section 3.3 (Designation of Nominated Targets) above shall apply mutatis mutandis to the nomination and designation of such Substitution Target to replace the then-designated Collaboration Target or Universal Cells Program Target, as applicable (the "Target Substitution Right") and a new Collaboration Research Program will be initiated in accordance with the terms of this Agreement. For clarity, once such Substitution Target is designated as the replacement Collaboration Target or Universal Cells Program Target (as applicable), such replaced Target shall no longer be a Collaboration Target or Universal Cells Program Target, as applicable. The JSC (with respect to replacement of a Collaboration Target) may elect to exercise its Target Substitution Right up to [\*\*\*] for each Collaboration Target (other than any Collaboration Target designated under Section 3.4 (Additional Collaboration Target Right), for which Collaboration Target the Target Substitution Right will only be available [\*\*\*]) (i.e., for a total of up to [\*\*\*] for Collaboration Targets, [\*\*\*] substitutions being possible for each of the [\*\*\*] initially designated Collaboration Targets and [\*\*\*] substitution being possible for the Collaboration Target designated if the Additional Collaboration Target Designation Right applies). Universal Cells (with respect to replacement of a Universal Cells Program Target) may elect to exercise its Target Substitution Right up to [\*\*\*] times for each Universal Cells Program Target (i.e., for a total of [\*\*\*] substitutions for Universal Cells Program Targets, [\*\*\*] substitutions being possible for each of the up to the [\*\*\*] initially designated Universal Cells Program Targets). The JSC may decide to make any additional Target substitutions with respect to any Collaboration Target or Universal Cells Program Target (as applicable) for which the Target Substitution Right has already been exhausted under this Section 4.6.1 (Pre-IND Substitutions for Collaboration Targets or Universal Cells Program Targets), but any such additional Target substitutions may be made only upon the mutual written agreement of the Parties (and not by decision of the JSC).

- 4.6.2 Phase 1 Clinical Trial Substitution Right for Collaboration Targets. After the completion of a Phase 1 Clinical Trial for a Collaboration Product Directed To a Collaboration Target, if the data resulting from such Phase 1 Clinical Trial indicates that such Collaboration Product does not meet the applicable Phase 1 Success Criteria, then, unless the Collaboration Target that such Collaboration Product is Directed To was designated as a Collaboration Product pursuant Section 3.4 (Additional Collaboration Target Right), the JRC, in consultation with the JDC shall have [\*\*\*] Target Substitution Right to nominate to the JSC for approval a Collaboration Substitution Target to replace such Collaboration Target that such Collaboration Product was Directed To. In such case, Section 3.2 (Nomination) and Section 3.3 (Designation of Nominated Targets) above shall apply *mutatis mutandis* to the nomination and designation of such Substitution Target and a new Collaboration Research Program will be initiated in accordance with the terms of this Agreement. The JSC shall have until the date that is [\*\*\*] days after the date that the Tables, Figures, and Listings from such Phase 1 Clinical Trial first become available to so notify the JRC of such substitution.
- **4.6.3 Effect of Substitution**. For clarity, once a Collaboration Substitution Target is designated as the new Collaboration Target and replaces the previously-designated Target pursuant to Section 4.6.1 (Pre-IND Substitution for Collaboration Targets or Universal Cells Program Targets) or Section 4.6.2 (Phase 1 Clinical Trial Substitution Right for Collaboration Targets), (a) such replaced Target shall no longer be a Collaboration Target and will instead be a Lapsed Target, and (b) notwithstanding any other provision to the contrary set forth in this Agreement, the Parties will have the right to begin a new Collaboration Research Program for such Collaboration Substitution Target, and such Collaboration Research Program will replace the Collaboration Research Program for the replaced Collaboration Target.
- **4.7 Progress Updates.** At each meeting of the JRC (with respect to nonclinical and pre-clinical Development activities) and of the JDC (with respect to Development activities relating to any clinical trials for a Collaboration Product, including each Phase 1 Clinical Trial), each Party will share with the JRC or JDC (as applicable) a summary regarding the activities conducted by or on behalf of such Party under each Collaboration Research Program since the last JRC or JDC meeting, sufficient for the JRC or JDC to assess each Party's progress under each Collaboration Research Program. Each Party will also promptly provide notice to the other Party, through the JRC or JDC, of any significant Development events under each Collaboration Research Program that the reporting Party reasonably believes materially impacts the Development activities of the other Party under such Collaboration Research Program or otherwise under this Agreement or that such Party reasonably believes would be of interest to the other Party.
- **4.8 Collaboration Research Program Records**. Each Party shall require that all work conducted by or on behalf of each Party in the course of a Collaboration Research Program be completely and accurately recorded, in sufficient detail and in good scientific manner, in separate laboratory notebooks. On reasonable notice, and at reasonable intervals, each Party shall have the right to inspect and copy all such records of the other Party reflecting work done under the Collaboration Research Program, to the extent reasonably required to carry out its respective obligations and to exercise its respective rights hereunder. Notwithstanding the definition of "Confidential Information," all such records shall constitute Confidential Information of the Party creating such records.

**4.9 End of Collaboration Research Program.** Unless otherwise agreed by the Parties and subject to the JSC's exercise of the [\*\*\*] Target Substitution Right pursuant to Section 4.6.2 (Phase 1 Clinical Trial Substitution Right for Collaboration Targets) if the Collaboration Product that was the subject of a Collaboration Research Program did not meet the Phase 1 Success Criteria set forth in the Collaboration Research Plan for such Collaboration Research Program, then after the completion of the first Phase 1 Clinical Trial for a Collaboration Product that is the subject of a Collaboration Research Program, the Collaboration Research Term for such Collaboration Research Program will expire and no further activities will be conducted in furtherance of such Collaboration Research Program.

# 4.10 Ongoing Development/Commercialization.

- **4.10.1 Continuing Development and Commercialization Notice.** Promptly after the Tables, Figures, and Listings from the first Phase 1 Clinical Trial for a Collaboration Product become available to the sponsoring Party and are provided to the non-sponsoring Party (the later of such dates, the "Phase 1 Data Availability Date"), the Parties, through the JDC, shall meet and discuss the results thereof. No later than [\*\*\*] after the Phase 1 Data Availability Date for a Collaboration Product, each Party shall notify the other Party in writing of whether such Party is interested in continuing to Develop, Manufacture, and Commercialize such Collaboration Product in the Territory pursuant to this Agreement (for each Collaboration Research Program, a "Continuing Development and Commercialization Notice").
- **4.10.2** Collaboration Profit-Share Products and Targets. If, with respect to a Collaboration Research Program, both Universal Cells and Adaptimmune each provide the other Party a Continuing Development and Commercialization Notice within the [\*\*\*] day time period noted in Section 4.10.1 (Continuing Development and Commercialization Notice), then the Collaboration Target that is the subject of such Collaboration Research Program shall immediately become a Collaboration Profit-Share Target, and the Collaboration Product that was the subject of such Phase 1 Clinical Trial shall immediately become deemed a Collaboration Profit-Share Product.

## 4.10.3 Unilateral Products and Targets.

(a) **Unilateral Universal Cells Product**. If, with respect to a Collaboration Research Program, Universal Cells provides Adaptimmune with a Continuing Development and Commercialization Notice within the [\*\*\*] day time period noted in Section 4.10.1 (Continuing Development and Commercialization Notice), but either (i) Adaptimmune provides Universal Cells written notice that Adaptimmune does not wish to continue to Develop, Manufacture, and Commercialize the Collaboration Product Directed To the Collaboration Target that is the subject of such Collaboration Research Program or (ii) Adaptimmune does not timely provide Universal Cells with a Continuing Development and Commercialization Notice within the [\*\*\*] day time period noted in Section 4.10.1 (Continuing Development and Commercialization Notice), then (i) the Collaboration Target that such Collaboration Product was Directed To shall immediately become a Unilateral Universal Cells Target and cease to be a Collaboration Target and (ii) the Collaboration Product that was the subject of such Phase 1 Clinical Trial shall immediately become a Unilateral Universal Cells Product and cease to be a Collaboration Product.

- (b) **Unilateral Adaptimmune Product.** If, with respect to a Collaboration Research Program, Adaptimmune provides Universal Cells with a Continuing Development and Commercialization Notice within the [\*\*\*] day time period noted in Section 4.10.1 (Continuing Development and Commercialization Notice), but either (i) Universal Cells provides Adaptimmune written notice that Universal Cells does not wish to continue to Develop, Manufacture, and Commercialize the Collaboration Product Directed To the Collaboration Target that is the subject of such Collaboration Research Program or (ii) Universal Cells does not timely provide Adaptimmune with a Continuing Development and Commercialization Notice within the [\*\*\*] day time period noted in Section 4.10.1 (Continuing Development and Commercialization Notice), then (i) the Collaboration Target that such Collaboration Product was Directed To shall immediately become a Unilateral Adaptimmune Target and cease to be a Collaboration Target and (ii) the Collaboration Product that was the subject of such Phase 1 Clinical Trial shall immediately become a Unilateral Adaptimmune Product and cease to be a Collaboration Product.
- **4.10.4 Lapsed Products and Targets**. If, with respect to a Collaboration Research Program, neither Party provides the other Party with a Continuing Development and Commercialization Notice within the [\*\*\*] day time period noted in Section 4.10.1 (Continuing Development and Commercialization Notice), or if each Party notifies the other Party in writing that it does not wish to continue to Develop, Manufacture, and Commercialize Collaboration Products Directed To the Collaboration Target that is the subject of such Collaboration Research Program, then (a) such Collaboration Target shall immediately become a "**Lapsed Target**" and cease to be a Collaboration Target and (b) all Collaboration Products Directed To such Collaboration Target shall immediately become Lapsed Products and cease to be Collaboration Products.
- **4.10.5 Technology Transfer.** In the event that a Collaboration Target becomes a Unilateral Target and the applicable Collaboration Product becomes a Unilateral Product under Sections 4.10.3 (Unilateral Products and Targets) or 5.3 (Development of and Clinical Trials for Collaboration Profit-Share Products), the Party relinquishing its right to such Collaboration Target and Collaboration Product shall use Commercially Reasonable Efforts to promptly transfer to the other Party, at the other Party's cost and expense, all Know-How necessary or reasonably useful for the other Party to Develop, Manufacture, and Commercialize such Unilateral Product, except for such material Know-How already in the receiving Party's possession. If so requested, the transferring Party agrees to provide reasonable technical assistance to the other Party, at the transferring party's expense, to enable the other Party to reasonably understand and utilize the transferred Know-How.

### **ARTICLE 5**

### CO-DEVELOPMENT OF COLLABORATION PROFIT-SHARE PRODUCTS

**5.1 Co-Development Plans.** Within [\*\*\*] days after the date a Collaboration Product that was the subject of the Phase 1 Clinical Trial under the applicable Collaboration Research Plan is designated as a Collaboration Profit-Share Product pursuant to Section 4.10.2 (Collaboration Profit-Share Products and Targets), the JDC shall prepare and send to the JSC for approval the Co-Development Plan for such Collaboration Profit-Share Product, including (a) an allocation between the Parties of responsibilities for Development activities for the applicable Collaboration

Profit-Share Product, (b) a timeline and plan for process development, chemistry, manufacturing, and controls activities and production with respect to the relevant Collaboration Profit-Share Product to be Developed under each Co-Development Plan, and (c) a budget of all costs and expenses to be incurred in the performance of activities under the applicable Co-Development Plan (each, a "Co-Development Budget"). Each Co-Development Plan shall be updated from time to time as agreed by the JDC but in any event at least once per Calendar Year.

- **5.2 Conduct of Co-Development Programs.** Each Party shall use Commercially Reasonable Efforts to conduct the activities for each Co-Development Program that are assigned to it under the Co-Development Plan for such Co-Development Program in accordance with the timeframes for completion of such activities set forth in such plan. The Parties acknowledge and agree that neither Party guarantees the success of tasks undertaken under a Co-Development Program.
- **Development of and Clinical Trials for Collaboration Profit-Share Products.** [\*\*\*] shall lead all Development Efforts for the Collaboration Profit-Share Products, including the conduct of (and shall be sponsor of) all clinical trials to be conducted for the Collaboration Profit-Share Products pursuant to each Co-Development Plan, including managing and owning all related INDs and other regulatory submissions and communications in connection therewith, and all Regulatory Approvals, unless the JSC agrees to delegate to [\*\*\*] the responsibility to conduct clinical trials, in which case the relevant Co-Development Plan shall specify each Party's roles in such clinical trials for such Collaboration Profit-Share Product. The Parties shall reasonably cooperate in connection with the conduct of all such Development activities and will negotiate in good faith to enter into pharmacovigilance agreements and quality assurance agreements before for the conduct of any Development activities for a Collaboration Profit-Share Product under a Co-Development Plan. At any time (A) if, following escalation pursuant to Section 2.2.4(b) (Escalation), the JSC and the Executive Officers are unable to agree on a Co-Development Plan or Co-Development Budget for a Collaboration Profit-Share Product, or any update thereto, or (B) following completion of a clinical trial under a Co-Development Plan, [\*\*\*], in its sole discretion, may deliver a notice to [\*\*\*] electing to opt-out of further Development of the applicable Collaboration Profit-Share Product under this Agreement (an "Opt-Out Notice"). Upon receipt of an Opt-Out Notice, [\*\*\*] may elect to either (i) continue to Develop, Manufacture, and Commercialize such Collaboration Profit-Share Product as a Unilateral [\*\*\*] Product, in which case, the Collaboration Profit-Share Target that such product was Directed To will thereafter become a Unilateral [\*\*\*] Target for purposes of this Agreement or (ii) to terminate the further Development, Manufacture, and Commercialization of such Collaboration Profit-Share Product, in which case the Collaboration Profit-Share Target that such product was Directed To will thereafter become a Lapsed Target for purposes of this Agreement. [\*\*\*] will provide written notice to [\*\*\*] of its election under the foregoing clause (i) or (ii) no later than [\*\*\*] days after the date of the applicable Opt-Out Notice, and if [\*\*\*] does not provide to [\*\*\*] notice of such election prior to the end of such [\*\*\*] day period the applicable Collaboration Profit-Share Target will thereafter become a Lapsed Target for purposes of this Agreement.
- **5.4 Regulatory**. All MAAs for the Collaboration Products (including Collaboration Profit-Share Products) shall be made by and in the name of Universal Cells or its Affiliate or sublicensee and all Regulatory Approval will be held in the name of Universal Cells or its Affiliate or sublicensee, in consultation with Adaptimmune through the JDC. In addition, unless otherwise

agreed by the JDC, all filings, submissions to, and correspondence with Regulatory Authorities regarding Regulatory Approval for any Collaboration Profit-Share Product shall be made by Universal Cells in consultation with Adaptimmune through the JDC. Universal Cells shall provide to Adaptimmune for review all substantive regulatory submissions and correspondence related to any Collaboration Profit-Share Product and will consider all timely comments from Adaptimmune thereon in good faith. To the extent permitted by the applicable Regulatory Authority, one representative of Adaptimmune may attend, as an observer, meetings with Regulatory Authorities in the Territory directly relating to any Collaboration Profit-Share Product. Adaptimmune shall reasonably cooperate with Universal Cells in connection with all such regulatory activities for the Collaboration Profit-Share Products.

- 5.5 **Development Updates**. At each meeting of the JDC, each Party will share with the JDC (as applicable) a summary regarding the activities conducted by or on behalf of such Party under each Co-Development Program since the last JDC meeting, sufficient for the JDC to assess each Party's Progress under the under the applicable plan. Each Party will also promptly provide notice to the other Party, through the JDC, of any significant Development events under the Co-Development Program that the reporting Party reasonably believes materially impacts the Development activities of the other Party under such Co-Development Program or otherwise under this Agreement or that such Party reasonably believes would be of interest to the other Party.
- **5.6 Development Costs**. The Parties will equally share Development Costs (as defined in <u>Schedule 11.3</u>) incurred in the Development of Collaboration Profit-Share Products under each Co-Development Program. <u>Schedule 11.3</u> specifies the calculation and manner for the sharing of such costs.

#### **ARTICLE 6**

### CO-COMMERCIALIZATION OF COLLABORATION PROFIT-SHARE PRODUCTS

6.1 Overview. The Parties, through the JCC, will collaborate to develop the Commercialization strategy for all Collaboration Profit-Share Products and otherwise to Commercialize the Collaboration Profit-Share Products in accordance with the applicable Co-Commercialization Plan, including the applicable Co-Commercialization Budget. [\*\*\*] will be responsible for Commercialization of Collaboration Profit-Share Products in the Territory in accordance with the applicable Co-Commercialization Plan, including distribution, sales, reporting to Regulatory Authorities, pricing and health systems-related activities, and all other Commercialization activities, provided, however, [\*\*\*]. For each Collaboration Profit-Share Product, the Parties agree to negotiate in good faith a Commercialization Agreement. Adaptimmune may also propose to Universal Cells that Adaptimmune provide such Commercialization support in major EU Countries in which case the JCC shall discuss such proposal in good faith. Universal Cells shall book all revenues from sales of Collaboration Profit-Share Products, subject to its obligations to share Profits with Adaptimmune as provided in Section 11.3 (Collaboration Profit-Share Products). The Parties shall share equally all Profits related to the Commercialization of the Collaboration Profit-Share Products, including all costs and expenses of Commercializing such products (to the extent in accordance with the applicable Co-Commercialization Budget).

- **6.2 Co-Commercialization Plans.** Within [\*\*\*] after the initiation of the first Pivotal Clinical Trial for a Collaboration Profit-Share Product, the JCC shall prepare and send to the JSC for approval a Co-Commercialization Plan for such Collaboration Profit-Share Product, including a Co-Commercialization Budget. Each Co-Commercialization Plan shall contain (a) the specific objectives for Commercializing the relevant Collaboration Profit-Share Product, including the anticipated launch dates in each Major Market, (b) the specific Commercialization activities to be performed by each Party in connection therewith, (c) a timeline and plan for production of commercial supplies of the relevant Collaboration Profit-Share Product, including back-up suppliers, inventory control, and commercial scale-up plans, labeling and packaging plans and artwork therefor, and (d) a budget of all costs and expenses to be incurred in the performance of activities under the applicable Co-Commercialization Plan (each a "Co-Commercialization Budget"). Each Co-Commercialization Plan shall be updated from time to time as agreed by the JCC, but in any event at least once per Calendar Year.
  - **6.3** [\*\*\*]
- **6.4 Conduct of Co-Commercialization Programs.** Each Party shall use Commercially Reasonable Efforts to conduct the activities for each Co-Commercialization Program that are assigned to it under the Co-Commercialization Plan for such Co-Commercialization Program in accordance with the timeframes for completion of such activities set forth in such plan. The Parties acknowledge and agree that neither Party guarantees the success of tasks undertaken under a Co-Commercialization Program.
- **6.5 Commercialization Updates.** At each meeting of the JCC, each Party will share with the JCC a summary regarding the activities conducted by or on behalf of such Party under each Co-Commercialization Program since the last JCC meeting, sufficient for the JCC to assess each Party's progress under the Co-Commercialization Program. Each Party will also promptly provide notice to the other Party, through the JCC, of any significant Commercialization events under any Co-Commercialization Program that the reporting Party reasonably believes materially impacts the Commercialization activities of the other Party under such Co-Commercialization Program or otherwise under this Agreement or that such Party reasonably believes would be of interest to the other Party.
- **6.6 Co-Commercialization Costs.** The Parties will equally share the costs of Commercializing Collaboration Profit-Share Products. <u>Schedule 11.3</u> specifies the calculation and sharing of costs and expenses and Profits in connection with the Commercialization of the Collaboration Profit-Share Products under each Co-Commercialization Program.

### **ARTICLE 7**

## DEVELOPMENT AND COMMERCIALIZATION OF UNILATERAL PRODUCTS

- 7.1 Unilateral Universal Cells Products.
- **7.1.1 Development Diligence Obligations**. Universal Cells shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval of all Unilateral Universal Cells Products in the Field in each Major Market, at its sole cost and expense.

**7.1.2 Commercialization Diligence Obligations**. After obtaining Regulatory Approval of a Unilateral Universal Cells Product in the Field in a country, Universal Cells shall use Commercially Reasonable Efforts to Commercialize such Unilateral Universal Cells Product in the Field in such country, at its sole cost and expense.

# 7.2 Unilateral Adaptimmune Products.

- **7.2.1 Development Diligence Obligations**. Adaptimmune shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval of all Unilateral Adaptimmune Products in the Field in each Major Market, at its sole cost and expense.
- **7.2.2 Commercialization Diligence Obligations**. After obtaining Regulatory Approval of a Unilateral Adaptimmune Product in the Field in a country, Adaptimmune shall use Commercially Reasonable Efforts to Commercialize such Unilateral Adaptimmune Product in the Field in such country, at its sole cost and expense.

### **ARTICLE 8**

## UNIVERSAL CELLS PRE-CLINICAL RESEARCH; UNIVERSAL CELLS PROGRAM

- **8.1 Permitted Pre-Clinical Research.** Notwithstanding any other provision of this Agreement, Universal Cells may conduct non-clinical research activities with respect to T-Cell differentiation at its sole cost and sole discretion for the purposes of Developing Universal Cells Program Products (the "Universal Cells Research Activities").
- **8.2 Performance of the Universal Cells Program.** Universal Cells shall have the right, but not the obligation, to Develop, Manufacture, Commercialize, and otherwise exploit up to two Universal Cells Program Products, each Directed To one of the two Universal Cells Program Targets in the Field in the Territory (the "Universal Cells Program"), at its sole cost and at its sole discretion. For clarity, an Universal Cells Program Product includes all reasonable improved and modified versions or iterations of the product that initially became an Universal Cells Program Product, whether intended to improve the safety, efficacy, or other properties of such Universal Cells Program Product.

#### **ARTICLE 9**

## LICENSES; OPTIONS; INTELLECTUAL PROPERTY

#### 9.1 Licenses.

**9.1.1 Universal Cells Research Activities License.** Adaptimmune hereby grants to Universal Cells a non-exclusive, worldwide, sublicensable (through multiple tiers), royalty-free, fully-paid license under all Adaptimmune-Licensed Universal Cells IP that is necessary or reasonably useful for Universal Cells to conduct the Universal Cells Research Activities; provided further that Universal Cells shall not have the right to grant sublicenses to practice Adaptimmune's proprietary Cell differentiation technology to any Third Party. For clarity such license does not include any license to Universal under any Adaptimmune Background IP other than the Adaptimmune-Licensed Universal Cells IP.

- 9.1.2 Grant to Universal Cells Under Adaptimmune-Licensed Universal Cells IP. Adaptimmune hereby grants to Universal Cells, effective upon the designation of a Universal Cells Program Target, an exclusive, worldwide, sublicensable (through multiple tiers), royalty-bearing, license under all Adaptimmune-Licensed Universal Cells IP that is necessary or reasonably useful for Universal Cells to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit the Universal Cells Program Product Directed To such Universal Cells Program Target in the Field in the Territory for the purpose of conducting activities pursuant to the Universal Cells Program and in accordance with this Agreement.
- **9.1.3 Grant-Back to Adaptimmune.** Universal Cells hereby grants to Adaptimmune a non-exclusive, sublicensable (through multiple tiers but solely to Third Parties developing, manufacturing, or commercializing products based on Cells with or for Adaptimmune), royalty-free license under the Universal Cells Grant-Back Patent Rights to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture and Commercialize products based on Cells.
- **9.1.4 Unilateral Universal Cells Product License**. Subject to the terms and conditions of this Agreement, Adaptimmune hereby grants to Universal Cells, effective upon the date a Collaboration Target becomes a Unilateral Universal Cells Target, an exclusive worldwide, sublicensable (through multiple tiers), royalty-bearing, license under all Adaptimmune-Licensed IP to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit the Unilateral Universal Cells Product Directed To such Unilateral Universal Cells Target in the Field in the Territory in accordance with this Agreement. For clarity, this license does not grant Universal Cells any right to, and Universal Cells shall not, use the Adaptimmune-Licensed IP to modify the Receptor in the applicable Unilateral Universal Cells Product; provided, that Universal Cells shall otherwise have the right to modify, improve, and otherwise alter the Unilateral Universal Cells Product (including the Receptor contained therein) in connection with its exploitation of the Unilateral Universal Cells Product in accordance with this Agreement.
- **9.1.5 Unilateral Adaptimmune Product License.** Subject to the terms and conditions of this Agreement, Universal Cells hereby grants Adaptimmune, effective upon the date a Collaboration Target becomes a Unilateral Adaptimmune Target, an exclusive worldwide, sublicensable (through multiple tiers), royalty-bearing, license under all Patent Rights within the Universal Cells Licensed IP to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit the Unilateral Adaptimmune Product Directed To such Unilateral Adaptimmune Target in accordance with this Agreement. For clarity, this license does not grant Adaptimmune any right to, and Adaptimmune shall not, use the Universal Cells Licensed IP to modify the Receptor in the applicable Unilateral Adaptimmune Product; provided, that Adaptimmune shall otherwise have the right to modify, improve, and otherwise alter the Unilateral Adaptimmune Product (including the Receptor contained therein) in connection with its exploitation of the Unilateral Adaptimmune Product in accordance with this Agreement.
  - 9.1.6 Co-Development and Co-Commercialization Licenses for Collaboration Products.

- (a) **License to Universal Cells.** Subject to the terms and conditions of this Agreement, Adaptimmune hereby grants to Universal Cells a worldwide, sublicensable (through multiple tiers, and subject to Adaptimmune's prior written consent as set forth in Section 9.3.1 (Sublicensing Rights)), royalty-bearing, license under the Adaptimmune Licensed IP to make, have made, use, sell, offer for sale, import, export, Develop, Commercialize, and otherwise exploit the Collaboration Products in accordance with the terms and conditions of this Agreement, including the applicable Collaboration Research Plan, Co-Development Plan, Co-Commercialization Plan, and Commercialization Agreement (as applicable). Such license shall be co-exclusive to Universal Cells, subject to Adaptimmune's retained rights under such Adaptimmune Background IP and Arising IP to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit the Collaboration Products in accordance with the terms and conditions of this Agreement.
- (b) License to Adaptimmune. Subject to the terms and conditions of this Agreement, Universal Cells hereby grants to Adaptimmune a worldwide, sublicensable (through multiple tiers, and subject to Universal Cells' prior written consent as set forth in Section 9.3.1 (Sublicensing Rights)), royalty-bearing, license under the Universal Cells Licensed IP to make, have made, use, sell, offer for sale, import, export, research, Develop, Manufacture, Commercialize, and otherwise exploit the Collaboration Products in accordance with the terms and conditions of this Agreement, including the applicable Collaboration Research Plan, Co-Development Plan, Co-Commercialization Plan, and Commercialization Agreement (as applicable). Such license shall be co-exclusive to Adaptimmune, subject to Universal Cell's retained rights under such Universal Cells Background IP and Arising IP to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit the Collaboration Products in accordance with the terms and conditions of this Agreement..

# 9.2 Options.

9.2.1 Unilateral Adaptimmune Product Elected License. Any time during the period commencing when a Collaboration Target becomes a Unilateral Adaptimmune Target (and the Collaboration Product Directed To such Target becomes a Unilateral Adaptimmune Product) in accordance this Agreement, and ending upon the date that is [\*\*\*] thereafter, (the "**Adaptimmune Election Period**"), Adaptimmune may elect, by providing written notice (a "Unilateral Adaptimmune Product Elected License Notice") to Universal Cells during such Adaptimmune Election Period specifying the specific Unilateral Adaptimmune Target (the "Elected **Unilateral Adaptimmune Target**") and the specific Contributed Technology used, contained, or incorporated into such Elected Unilateral Adaptimmune Product Directed To such Target it wishes to obtain license rights to receive from Universal Cells, an exclusive, worldwide, sublicensable (through multiple tiers), royalty-bearing, license under all (a) Universal Cells Background IP and (b) Arising IP Controlled by Universal Cells, in each case (a) and (b), that relates to such Contributed Technology and is necessary or reasonably useful for Adaptimmune to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit such Elected Unilateral Adaptimmune Product solely for the purpose of conducting such activities with respect to such Unilateral Adaptimmune Product (the "Elected Unilateral Adaptimmune Product License"). Subject to the terms and conditions of this Agreement, upon receipt of a Unilateral Adaptimmune Product Elected License Notice, Universal Cells shall confirm whether an exclusive Elected Unilateral Adaptimmune Product License is then

available, and if not, provide a description of any applicable Universal Cells Impediment. If a Universal Cells Impediment is identified, and the Parties agree on certain adjustments necessary to enable a variation of the Elected Unilateral Adaptimmune Product License to be granted, the Parties shall enter into an agreement specifying any adjustments to the Elected Unilateral Adaptimmune Product License necessary to address such Universal Cells Impediment. If the Parties enter into such an agreement, or if no Universal Cells Impediment exists, then Universal Cells shall grant to Adaptimmune, and hereby does, grant to Adaptimmune the Elected Unilateral Adaptimmune Product License subject to any such mutually agreed modifications.

**Universal Cells Program Product Elected License.** If a Universal Cells Program Product uses (or is engineered using) Adaptimmune's proprietary T-Cell differentiation process, then at any time during the period commencing when a Collaboration Target becomes a Universal Cells Program Target (and the Collaboration Product Directed To such Target becomes a Universal Cells Program Product) in accordance with this Agreement and ending upon the date that is [\*\*\*] thereafter (the "Universal Cells Election Period"), Universal Cells may, by providing written notice (a "Universal Cells Program Product Elected License Notice") to Adaptimmune during such Universal Cells Election Period specifying the specific Universal Cells Program Target concerned (the "Elected Universal Cells Program Target"), elect to receive from Adaptimmune an exclusive, worldwide, sublicensable (through multiple tiers), royalty-bearing, license under all (a) Adaptimmune Background IP and (b) Arising IP Controlled by Adaptimmune that, in each case ((a) and (b)), is (i) specific to the Adaptimmune's proprietary T-Cells differentiation process and (ii) necessary or reasonably useful for Universal Cells to make, have made, use, sell, offer for sale, import, export, Develop, Manufacture, Commercialize, and otherwise exploit such Universal Cells Program Product solely for the purpose of conducting such activities with respect to such Universal Cell Program Product in accordance with the terms and conditions of this Agreement (the "Elected Universal Cells Program Product License"). Upon receipt of a Universal Cells Program Product Elected License Notice, Adaptimmune shall confirm whether an exclusive Elected Universal Cells Program Product License is then available, and if not, provide a description of any basis for it not being then available (e.g., certain rights have been licensed out in a manner precluding the grant of the exclusive Elected Universal Cells Program Product License) (an "Adaptimmune Impediment"). If an Adaptimmune Impediment is identified, and the Parties agree on certain adjustments necessary to enable a variation of the Elected Universal Cells Program Product License to be granted at such time, the Parties shall enter into an agreement specifying any adjustments to the Elected Universal Cells Program Product License necessary to address such Adaptimmune Impediment. If the Parties enter into such an agreement, or if no Adaptimmune Impediment then exists, then Adaptimmune shall grant to Universal Cells, and hereby grants to Universal Cells, the Elected Universal Cells Program Product License subject to any such mutually agreed modifications. For clarity, the license pursuant to this Section 9.2.2 does not include any rights under any other Adaptimmune Background IP or Arising IP other than that which is specific to Adaptimmune's proprietary T-Cell differentiation process, and, without limitation, does not include Patent Rights covering or Know-How relating to engineering of TCRs.

## 9.3 Sublicense Rights.

**9.3.1 Sublicensing Rights**. Wherever in this Agreement either Party is granted the right to grant sublicenses, such Party may exercise such right without obtaining the

prior approval of the other Party unless otherwise expressly set forth herein, provided that such sublicense is granted pursuant to a written agreement that subjects such sublicensee to all relevant terms, conditions, restrictions, and limitations of this Agreement. [\*\*\*]. Each Party may sublicense its rights under Section 9.1.6 (Co-Development and Co-Commercialization Licenses for Collaboration Products) only with the prior written consent of the other Party, not to be unreasonably withheld, delayed or conditioned (provided, that a Party may grant a limited sublicense to any contract research organizations, contract manufacturing organizations, clinical research organizations, or other subcontractors engaged by such Party to perform such Party's obligations with respect to the Collaboration Products without such prior written consent and in accordance with Section 17.15 (Subcontracting; Performance by Affiliates).

9.3.2 [\*\*\*].

### 9.4 Retained Rights.

- **9.4.1 Universal Cells Retained Rights**. With respect to this Agreement, any rights of Universal Cells not expressly granted to Adaptimmune under the provisions of this Agreement or the Existing Agreement shall be retained by Universal Cells.
- **9.4.2 Adaptimmune Retained Rights.** With respect to this Agreement, any rights of Adaptimmune not expressly granted to Universal Cells under the provisions of this Agreement or the Existing Agreement shall be retained by Adaptimmune.
- **9.5 Section 365(n) Of The Bankruptcy Code.** All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any licensed intellectual property not already in such Party's possession and necessary for such Party to enjoy the rights granted to it under such license, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.
- **9.6 No Implied Licenses or Rights.** Except as expressly provided in this Agreement, neither Party shall have any license or other interest in any intellectual property rights Controlled by the other Party.
  - 9.7 Ownership of Arising Inventions and Intellectual Property Rights.

#### 9.7.1 Collaboration Inventions.

(a) Adaptimmune Technology Inventions. As between the Parties, Adaptimmune shall solely own all Adaptimmune Technology Inventions and all Patent Rights covering such inventions. Universal Cells hereby assigns, and will assign, to Adaptimmune all of its rights, title, and interest in, to, and under the Adaptimmune Technology Inventions, and all Patent Rights covering such inventions.

- (b) **Universal Cells Technology Inventions**. As between the Parties, Universal Cells shall solely own all Universal Cells Technology Inventions and all Patent Rights covering such inventions. Adaptimmune hereby assigns, and will assign, to Universal Cells all of its rights, title, and interest in, to, and under the Universal Cells Technology Inventions, and all Patent Rights covering such inventions .
- (c) **PSC Inventions**. As between the Parties, Universal Cells shall solely own all PSC Inventions and all Patent Rights covering such inventions. Adaptimmune hereby assigns to Universal Cells all of its rights, title, and interest in, to, and under the PSC Inventions and all Patent Rights covering such inventions.
- (d) **Collaboration Joint Inventions**. As between the Parties, the Parties shall jointly own all Collaboration Joint Inventions and all Patent Rights covering such inventions. Each Party hereby assigns, and will assign, to the other Party an undivided, equal joint interest in, to, and under the Collaboration Joint Inventions, and all Patent Rights covering such inventions. Subject to the rights and licenses granted herein and pursuant to the Existing Agreement, each Party shall have the right, without any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign, or otherwise exploit the Collaboration Joint Inventions and Patent Rights covering such inventions, and each Party hereby waives any right it may have under the Applicable Laws of any jurisdiction to require such approval, consent, or accounting. Each Party agrees to cooperate with the other Party, as reasonably requested, and to take such actions as may be required to give effect to this Section 9.7 (Ownership of Arising Inventions and Intellectual Property Rights) in a particular country within the Territory.
- **9.7.2 Universal Cells Program Inventions**. As between the Parties, Universal Cells shall solely own all Universal Cells Program Inventions and all Patent Rights covering such inventions.

#### 9.8 Patent Prosecution and Maintenance.

- **9.8.1 Adaptimmune Background IP**. As between the Parties, Adaptimmune shall have the sole right, and shall use Commercially Reasonable Efforts, to control the filing, prosecution, and maintenance of all Patent Rights within the Adaptimmune Background IP ("**Adaptimmune Background Patents**") including such Patents Rights within the Adaptimmune Background IP solely related to the Adaptimmune Technology, at its sole cost and using counsel of its choice, including the conduct of re-examinations, reviews, reissues, and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, post-grant reviews, *inter partes* reviews, and other similar proceedings with respect to such Patent Rights.
- **9.8.2 Universal Cells Background IP.** As between the Parties, Universal Cells shall have the sole right, and shall use Commercially Reasonable Efforts, to control the filing, prosecution, and maintenance of all Patent Rights within the Universal Cells Background IP, at its sole cost and using counsel of its choice ("**Universal Cells Background Patents**"), including the conduct of re-examinations, reviews, reissues and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, post-grant reviews, inter

partes reviews, and other similar proceedings with respect to such Patent Rights, subject to the rights granted by Universal Cells to Adaptimmune under the Background Agreement with respect to the filing, prosecution, and maintenance thereof.

- **9.8.3 Arising Core Adaptimmune Patents**. As between the Parties, Adaptimmune shall have the sole right, and shall use Commercially Reasonable Efforts, to control the filing, prosecution, and maintenance of all Patent Rights claiming the Adaptimmune Technology Inventions ("**Arising Core Adaptimmune Patents**"), including the conduct of re-examinations, reviews, reissues, and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, post-grant reviews, inter partes reviews, and other similar proceedings with respect to such Patent Rights, at Adaptimmune's sole cost and using counsel of its choice.
- **9.8.4 Arising Core Universal Cells Patents**. As between the Parties, Universal Cells shall have the sole right, and shall use Commercially Reasonable Efforts, to control the filing, prosecution, and maintenance of all Patent Rights claiming Universal Cells Technology Inventions or PSC Inventions ("**Arising Core Universal Cells Patents**"), including the conduct of re-examinations, reviews, reissues and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, post-grant reviews, inter partes reviews, and other similar proceedings with respect to such Patent Rights, at Universal Cells' sole cost and using counsel of its choice.
- **9.8.5 Collaboration Joint IP.** This Section 9.8.5 (Collaboration Joint IP)shall apply with respect to the filing, prosecution, and maintenance of the Patent Rights claiming the Collaboration Joint Inventions ("Collaboration Joint Patent Rights"), including the conduct of re-examinations, reviews, reissues and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, postgrant reviews, inter partes reviews, and other similar proceedings with respect to such Patent Rights. Subject to Section 9.8.6 (Modification for Unilateral Adaptimmune Products) and Section 9.8.7 (Modification for Unilateral Universal Cells Products), as between the Parties, [\*\*\*] shall have the first right, but not the obligation, to control the filing, prosecution, and maintenance of the Collaboration Joint Patent Rights, using outside counsel of its choice.
  - (a) [\*\*\*].
  - (b) [\*\*\*].
- (c) All costs and expenses incurred by Party in connection with the filing, prosecution, and maintenance of the Collaboration Joint Patent Rights shall be shared equally by the Parties.
- **9.8.6 Modification for Unilateral Adaptimmune Products.** Notwithstanding Section 9.8.5 (Collaboration Joint IP), upon a Collaboration Target becoming a Unilateral Adaptimmune Target, Adaptimmune shall have the sole right, and shall use Commercially Reasonable Efforts, to file, prosecute, and maintain those Collaboration Joint Patent Rights that contain claims solely and specifically directed to Unilateral Adaptimmune Products or are solely and specifically directed to a Unilateral Adaptimmune Target ("**Unilateral**

Adaptimmune Product-Specific Patents"), including the conduct of re-examinations, reviews, reissues, and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, post-grant reviews, inter partes reviews, and other similar proceedings with respect to such Patent Rights, at Adaptimmune's sole cost and using counsel of its choice. To the extent Universal Cells was previously controlling the prosecution of any Unilateral Adaptimmune Product-Specific Patents at the time immediately prior to such Collaboration Target becoming a Unilateral Adaptimmune Target pursuant to Section 9.8.5 (Collaboration Joint IP), Universal Cells shall transfer all files and documents in Universal Cells' possession and Control necessary for the prosecution and maintenance of such Unilateral Adaptimmune Product-Specific Patents in such country to Adaptimmune. Upon a Collaboration Target becoming a Unilateral Adaptimmune Target, the Parties shall discuss and agree upon which Party will have the prosecution and maintenance of Collaboration Joint Patent Rights that are not Unilateral Adaptimmune Product-Specific Patents.

Modification for Unilateral Universal Cells Products. Notwithstanding Section 9.8.5 (Collaboration Joint IP), upon a Collaboration Target becoming a Unilateral Universal Cells Target, Universal Cells shall have the sole right, and shall use Commercially Reasonable Efforts, to file, prosecute, and maintain those Collaboration Joint Patent Rights that contain claims solely and specifically directed to Unilateral Universal Cells Products or are solely and specifically directed to a Unilateral Universal Cells Target ("Unilateral Universal Cells **Product-Specific Patents**"), including the conduct of re-examinations, reviews, reissues, and the like with respect to such Patent Rights, and the conduct of interferences, the defense of oppositions, oppositions, post-grant reviews, inter partes reviews, and other similar proceedings with respect to such Patent Rights, at Universal Cell's sole cost and using counsel of its choice. To the extent Adaptimmune was previously controlling the prosecution of any Unilateral Universal Cells Product-Specific Patents at the time immediately prior to such Collaboration Target becoming a Unilateral Universal Cells Target pursuant to Section 9.8.5 (Collaboration Joint IP), Adaptimmune shall transfer all files and documents in Adaptimmune's possession and Control necessary for the prosecution and maintenance of such Unilateral Universal Cells Product-Specific Patents in such country to Universal Cells. Upon a Collaboration Target becoming a Unilateral Universal Cells Target, the Parties shall discuss and agree upon which Party will have the prosecution and maintenance of Collaboration Joint Patent Rights that are not Unilateral Adaptimmune Product-Specific Patents.

**9.8.8** Coordination of Prosecution. The Parties shall cooperate to coordinate same-day patent application filings for Arising IP, as requested by the other party, for any provisional or non-provisional patent applications (but for clarity not any continuations, continuations-in-part or divisionals) as for patent application filings within the Universal Cells Background IP or Adaptimmune Background IP that are directed to subject matter inventions that were used to identify, produce or develop a Product during the performance of activities under this Agreement to avoid jeopardizing patentability of any such Patent Right.

#### 9.9 Patent Enforcement.

**9.9.1 Universal Cells Background IP**. As between the Parties, Universal Cells shall have the sole right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Patent Rights within the Universal Cells Background IP (subject to

the Existing Agreement), against infringement by a Third Party product that is competitive with any Collaboration Product, Unilateral Product, or Universal Cells Program Product, at its sole cost and expense (except that costs of enforcing such Patent Rights against Third Party products competitive with Collaboration Products shall be shared equally by the Parties) and using counsel of its choice. [\*\*\*].

(a) [\*\*\*].

### 9.9.2 Adaptimmune Background IP

- (a) **Composition of Matter Patents.** As between the Parties, with respect to Patent Rights within the Adaptimmune Background IP that solely claim the composition of matter of a given Unilateral Universal Cells Product, Collaboration Product, Universal Cells Program Product, or Unilateral Adaptimmune Product (as applicable), and provided that the Arising IP does not then-currently contain any Patent Right claiming the composition of matter of such Unilateral Universal Cells Product, Collaboration Product, Universal Cells Program Product, or Unilateral Adaptimmune Product (as applicable):
- (i) [\*\*\*] shall have the sole right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Unilateral Universal Cells Program Product, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (ii) [\*\*\*] shall have the sole right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (iii) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Collaboration Product, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within ninety (90) days (or such longer time periods as the Parties may agree) after receiving notice of such infringement from [\*\*\*], or if applicable, no later than [\*\*\*] days prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. [\*\*\*].
- (iv) Neither Party shall have the right to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Universal Cells Program Product.
- (b) **Other Patents.** As between the Parties, with respect to Patent Rights within the Adaptimmune Background IP that do not claim the composition of matter of a given Unilateral Universal Cells Product, Collaboration Product, Universal Cells Program Product, or Unilateral Adaptimmune Product (as applicable):

- (i) Adaptimmune shall have the sole right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (ii) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Collaboration Product, using counsel that is mutually agreed to by [\*\*\*]. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within [\*\*\*] (or such longer time periods as the Parties may agree) after receiving notice of such infringement from [\*\*\*] or if applicable, no later than [\*\*\*] prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. [\*\*\*].
- (iii) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Unilateral Universal Cells Product, at its sole cost and expense and using counsel of its choice. [\*\*\*]. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within [\*\*\*] after receiving notice of such infringement from [\*\*\*], or if applicable, no later than [\*\*\*] days prior to the applicable expiration date for the initiation of such action under Applicable Law (unless otherwise agreed by the Parties in writing), then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (iv) <u>Neither Party shall have the right</u> to initiate, prosecute and control any legal action or proceeding enforcing such Patent Rights against infringement by a Third Party product that is competitive with any Universal Cells Program Product.

# 9.9.3 Arising Core Universal Cells Patents.

- (a) As between the Parties, Universal Cells shall have the sole right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Arising Core Universal Cells Patents, against infringement by a Third Party product that is competitive with any Universal Cells Program Product, Unilateral Universal Cells Product or Collaboration Product, at its sole cost and expense (except that costs of enforcing such Patent Rights against Third Party products competitive with Collaboration Products shall be shared equally by the Parties) and using counsel of its choice. [\*\*\*].
- (b) [\*\*\*] shall have the sole right, in consultation with [\*\*\*], to initiate, prosecute and control any legal action or proceeding enforcing such the Arising Core Universal Cells Patents against infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product, at its sole cost and expense and using counsel of its choice.
  - (i) [\*\*\*].

## **9.9.4 Arising Core Adaptimmune Patents.** As between the Parties:

- (a) [\*\*\*] shall have the sole right, in consultation with [\*\*\*], but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Arising Core Adaptimmune Patents against infringement by a Third Party product that is competitive with any Universal Cells Program Product, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (b) [\*\*\*] shall have the sole right, in consultation with [\*\*\*], but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Arising Core Adaptimmune Patents against infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (c) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Arising Core Adaptimmune Patents against infringement by a Third Party product that is competitive with any Collaboration Product, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection [\*\*\*] after receiving notice of such infringement from [\*\*\*], or if applicable, no later than [\*\*\*] (or such longer time periods as the Parties may agree) prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. [\*\*\*].
- (d) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing such Arising Core Adaptimmune Patents against infringement by a Third Party product that is competitive with any Unilateral Universal Cells Product, at its sole cost and expense and using counsel of its choice. [\*\*\*]. If Universal Cells does not elect to bring such legal action to abate such infringement described in this subsection [\*\*\*] days after receiving notice of such infringement from [\*\*\*], or if applicable, no later than [\*\*\*] (or such longer time periods as the Parties may agree) prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, at its sole cost and expense and using counsel of its choice. [\*\*\*].

### **9.9.5** Collaboration Joint Patent Rights. As between the Parties:

- (a) [\*\*\*] shall have the sole right, in consultation with [\*\*\*], but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Collaboration Joint Patent Rights against infringement by a Third Party product that is competitive with any Universal Cells Program Product, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (b) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Collaboration Joint Patent Rights against infringement by a Third Party product that is competitive with any Unilateral Universal

Cells Product, at its sole cost and expense and using counsel of its choice. [\*\*\*]. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within [\*\*\*] after receiving notice of such infringement from [\*\*\*], or if applicable, no later than thirty (30) days prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, at its sole cost and expense and using counsel of its choice. [\*\*\*].

- (c) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing the Collaboration Joint Patent Rights against infringement by a Third Party product that is competitive with any Collaboration Product, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within [\*\*\*] (or such longer time periods as the Parties may agree) after receiving notice of such infringement from Adaptimmune, or if applicable, no later than [\*\*\*] prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, using counsel that is mutually agreed to by Universal Cells and Adaptimmune. [\*\*\*].
- (d) With respect to infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product:
- (i) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Collaboration Joint Patent Rights that solely claim the Unilateral Adaptimmune Product ("Unilateral Adaptimmune Product-Specific Collaboration Joint Patent Rights") against infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product, at its sole cost and expense and using counsel of its choice. [\*\*\*]. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within [\*\*\*] days after receiving notice of such infringement from Universal Cells or if applicable, no later than [\*\*\*] days prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, at its sole cost and expense and using counsel of its choice. [\*\*\*].
- (ii) [\*\*\*] shall have the first right, but not the obligation, to initiate, prosecute and control any legal action or proceeding enforcing Collaboration Joint Patent Rights that are not Unilateral Adaptimmune Product-Specific Collaboration Joint Patent Rights against infringement by a Third Party product that is competitive with any Unilateral Adaptimmune Product, at its sole cost and expense and using counsel of its choice. [\*\*\*]. If [\*\*\*] does not elect to bring such legal action to abate such infringement described in this subsection within [\*\*\*] (or such longer time periods as the Parties may agree) after receiving notice of such infringement from Adaptimmune or if applicable, no later [\*\*\*] prior to the applicable expiration date for the initiation of such action under Applicable Law, then [\*\*\*] shall have the right but not the obligation, to initiate, prosecute, and control any such action or proceeding, at its sole cost and expense and using counsel of its choice. [\*\*\*].

- **9.9.6 Universal Cells Program IP.** Universal Cells shall have the sole right, but not the obligation, to enforce the Patent Rights within the Universal Cells Program IP against Third Party infringement.
- **9.9.7 Cooperation; Settlement**. The Party bringing the enforcement action under this Section 9.9 (Patent Enforcement) shall be deemed the "**Enforcing Party**". At the request and expense of the Enforcing Party bringing an enforcement action under Section 9.9 (Patent Enforcement), the other Party shall provide reasonable assistance in connection therewith, including by executing appropriate documents, cooperating in discovery and joining as a party to the action if required to maintain standing. In connection with any such proceeding, the Enforcing Party shall keep the other Party reasonably informed on the status of such action and shall not enter into any settlement granting any sublicense under any Patent Rights Controlled by the other Party outside of the rights such Party would otherwise have under Section 9.3 (Sublicense Rights) or admitting the invalidity or unenforceability of, or otherwise impairing the other Party's rights with respect to, the Patent Rights subject to such enforcement action without the prior written consent of the other Party.
- **9.9.8 Invalidity Actions**. If in any patent enforcement action commenced pursuant to Section 9.9 (Patent Enforcement) the Third Party defendant asserts that an asserted Patent Right is invalid or unenforceable, then, if the Enforcing Party does not own such Patent Right, then the other Party may join such action as a Party and may control the defense of such assertion in coordination and collaboration with the Enforcing Party.

# 9.10 Defense and Settlement of Third Party Claims.

**9.10.1 Collaboration Profit-Share Product.** If any Collaboration Product, Unilateral Product, or Universal Cells Program Product being Developed or Commercialized by a Party or its Affiliates or sublicensees pursuant to this Agreement becomes the subject of a Third Party's claim or assertion of infringement of Patent Rights owned or controlled by such Third Party, then the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"). Neither Party shall enter into any settlement of any claim described in this Section 9.10.1 (Collaboration Profit-Share Products) that admits to the invalidity or unenforceability of any Patent Right Controlled by the other Party (or otherwise affects the scope, validity or enforceability of such Patent Right), incurs any financial liability on the part of the other Party or requires an admission of liability, wrongdoing or fault on the part of the other Party without such other Party's written consent. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's request and expense. Additionally, if the Defending Party is not the Party that Controls the Patent Right in question, then the other Party shall have the right to join any such action using counsel of its choice, at such Party's sole expense (provided that if such action involves Collaboration Products, then if such action arises during the time period in which such Collaboration Product is a Collaboration Profit-Share Product, such costs will be included in the Program Costs and the calculation of Profit pursuant to Schedule 11.3).

#### **ARTICLE 10**

#### **EXCLUSIVITY; PLATFORM**

#### **10.1** Exclusivity Covenants.

**10.1.1 Collaboration Targets.** On a per-Target basis, during the time period starting the date on which a Target is designated as Collaboration Target (and for clarity continuing while a Target is a Collaboration Profit-Share Target) pursuant to this Agreement and ending when such Target becomes a Lapsed Target or a Unilateral Target, or this Agreement otherwise terminates or expires with respect to such Target, neither Party nor its Affiliates shall, alone or in collaboration with or through a Third Party, other than in the scope of this Agreement, engage in the Development, Manufacture, Commercialization, or other exploitation of any Products Directed To such Collaboration Target in the Field and in the Territory, or grant any rights to any Third Party to do the same ([\*\*\*]).

(a) [\*\*\*].

**10.1.2 Universal Cells Program Targets.** On a per-Target basis, during the time period starting when Target is designated as a Universal Cells Program Target pursuant to this Agreement and ending when this Agreement terminates or expires with respect to such Target, neither Adaptimmune nor its Affiliates shall, alone or in collaboration with or through a Third Party, engage in the Development, Manufacture, Commercialization, or other exploitation of any product containing a Cell engineered to express a Receptor that is in the same Receptor Class as the Receptor of the Universal Cells Program Product Directed To such Universal Cells Program Target as notified by Universal Cells to Adaptimmune upon designation of such Universal Cells Program Target in the Field and in the Territory, or grant any rights to any Third Party to do the same.

(a) [\*\*\*].

**10.1.3 Unilateral Adaptimmune Targets.** On a per-Target basis, during the time period starting when Target becomes a Unilateral Adaptimmune Target pursuant to this Agreement and for so long as Adaptimmune continues to Develop or Commercialize the Unilateral Adaptimmune Product Directed To such Target pursuant to this Agreement or until this Agreement expires with respect to such Target, neither Universal Cells nor its Affiliates shall, alone or in collaboration with or through a Third Party, other than solely to fulfill its obligations under this Agreement in connection with the transition of a Collaboration Target to a Unilateral Adaptimmune Target, engage in the Development, Manufacture, Commercialization, or other exploitation of any Products Directed To such Unilateral Adaptimmune Target in the Field in the Territory, or grant any rights to any Third Party to do the same (subject to Universal Cells' right to conduct the Universal Cells Research Activities).

(a) [\*\*\*]

**10.1.4 Unilateral Universal Cells Targets**. On a per-Target basis, during the time period starting when Target becomes a Unilateral Universal Cells Target pursuant to this Agreement and for so long as Universal Cells continues to Develop or Commercialize the

Unilateral Universal Cells Product Directed To such Target pursuant to this Agreement or until this Agreement expires with respect to such Target, neither Adaptimmune nor its Affiliates shall, alone or in collaboration with or through a Third Party, other than solely to fulfill its obligations under this Agreement in connection with the transition of a Collaboration Target to a Unilateral Universal Cells Target, engage in the Development, Manufacture, Commercialization, or other exploitation of any Products Directed To such Unilateral Universal Cells Target in the Field in the Territory, or grant any rights to any Third Party to do the same.

(a) [\*\*\*].

## 10.2 Platform Reporting; Clinical Trial Data.

- **10.2.1** From and after the date upon which the first Phase 1 Clinical Trial commences for a Product, on a semiannual basis, each Party shall provide to the other Party through the JSC a written summary of any results, data or information obtained with respect to Collaboration Products, Unilateral Products or Universal Cells Program Products that reasonably indicates that there may be potential adverse effects on patients attributable to common elements of Products (e.g., components of a Receptor, the PSC relevant to the Product), so that the other Party remains reasonably informed with respect thereto. Such reports shall be subject to Third Party confidentiality obligations but shall include information relating to the relevant common element, the nature of the potential adverse effect, and any assessment of mitigation approaches therefor.
- **10.2.2** Clinical trial data (a) generated by Adaptimmune for the Collaboration Products or Unilateral Adaptimmune Products that relates specifically to the Universal Cells Technology or any Contributed Technology and (b) generated by Universal Cells for the Collaboration Products or Unilateral Universal Cells Products that relates specifically to the Adaptimmune Technology shall be co-owned by the Parties.
- 10.3 Acquisitions by Third Parties. Neither Party will be in breach of the restrictions applicable to such Party set forth in Section 10.1 (Exclusivity Covenants) if such Party undergoes a Change of Control with a Third Party (together with such Third Party and its Affiliates following the closing of the applicable Change of Control transaction, the "Acquired Party") that is (either directly or through an Affiliate, or in collaboration with the Third Party) performing activities with respect to one or more products that would otherwise cause the Party undergoing the Change of Control to be in violation of the terms of Section 10.1 (Exclusivity Covenants) ("Competitive Activities") applicable to such Party upon the closing of such Change of Control transaction, and such Acquired Party may continue to perform such Competitive Activities with respect to such products after such Change of Control transaction; as long as [\*\*\*].

#### **ARTICLE 11**

## FINANCIAL PROVISIONS

**11.1 Upfront Payment**. As partial consideration for the rights granted by Adaptimmune to Universal Cells pursuant to the terms of this Agreement and for Adaptimmune undertaking its obligations and responsibilities under this Agreement, Universal Cells shall pay to Adaptimmune

a non-refundable, non-creditable payment equal to fifty million dollars (\$50,000,000) within five (5) business days after the Effective Date.

### 11.2 Milestone Payments.

**11.2.1 Development and Regulatory Milestones Payable to Adaptimmune.** Universal Cells shall pay to Adaptimmune the following one-time milestone payments upon the first achievement of the following development and regulatory milestone events by Universal Cells, its Affiliates, or its sublicensees for each relevant Product that is Directed To a Collaboration Profit-Share Target, Elected Universal Cells Program Target, or Unilateral Universal Cells Target, as applicable, as set forth in the table below.

	Milestone amount payable per Product Directed To Target		
Milestone event	Collaboration Profit-Share Product	Elected Universal Cells Program Product	Unilateral Universal Cells Product
[***]	[***]	NA	NA
[***]	NA	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total Milestones Payable per distinct Target within such Target type	[***]	[***]	[***]

11.2.2 Development and Regulatory Milestones Payable to Universal Cells. Adaptimmune shall pay to Universal Cells the following one-time milestone payments upon the first achievement of the following development and regulatory milestone events by Adaptimmune, its Affiliates, or its sublicensees for each Product that is Directed To an Elected Unilateral Adaptimmune Product as set forth in the table below where (a) the Elected Unilateral Adaptimmune Product incorporates or is derived from Contributed Technology in accordance with Section 3.5 (Contributed Technology), (b) the sequence of such Receptor is covered by a Valid Claim of a Patent Right Controlled by Universal Cells or its Affiliates, and (c) Universal Cells has granted Adaptimmune an Elected Unilateral Adaptimmune Product License in accordance with Section 9.2.1 (Unilateral Adaptimmune Product Elected License) pursuant to which such Patent Rights are licensed to Adaptimmune. For all other Elected Unilateral Adaptimmune Products (e.g. one containing such a Receptor that is not covered by any Patent Right Controlled by Universal Cells or its Affiliates), no milestones under this Section 11.2.2 shall be payable.

Milestone Event	Milestone Amount per Product Directed To an Elected Unilateral Adaptimmune Target
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total Milestones Payable per distinct Elected Unilateral Adaptimmune Target	[***]

11.2.3 Sales Milestones Payable to Adaptimmune. Universal Cells shall pay to Adaptimmune the following one-time milestone payments upon the first achievement of the following sales milestone events set forth in the table below when the aggregated annual Net Sales (measured on a Calendar Year basis) of all (a) Unilateral Universal Cells Products and (b) Elected Universal Cells Program Products (cumulatively) sold in the Territory in a given Calendar Year by Universal Cells, its Affiliates, or its sublicensees first reach the corresponding threshold values indicated in the table below.

Annual Net Sales of all (a) Unilateral Universal Cells Products and (b) Elected Universal Cells Program Products	Sales Milestone Payment Amount
[***]	[***]
[***]	[***]
[***]	[***]
Total sales milestones payable	[***]

11.2.4 Sales Milestones Payable to Universal Cells. Adaptimmune shall pay to Universal Cells the following one-time milestone payments upon the first achievement of the following sales milestone events set forth in the table below when the aggregated annual Net Sales (measured on a Calendar Year basis) of all Elected Unilateral Adaptimmune Products (cumulatively) sold in the Territory in a given Calendar Year by Adaptimmune, its Affiliates, or its sublicensees first reach the corresponding threshold values indicated in the table below where (a) the Elected Unilateral Adaptimmune Product incorporates or is derived from Contributed Technology in accordance with Section 3.5 (Contributed Technology), (b) the sequence of such Receptor is covered by a Valid Claim of a Patent Right Controlled by Universal Cells or its Affiliates, and (c) Universal Cells has granted Adaptimmune an Elected Unilateral Adaptimmune Product License in accordance with Section 9.2.1 (Unilateral Adaptimmune Product Elected License) pursuant to which such Patent Rights are licensed to Adaptimmune. For all other Elected Unilateral Adaptimmune Products (e.g. one containing such a Receptor that is not covered by any Patent Right Controlled by Universal Cells or its Affiliates), no milestones under this Section 11.2.4 shall be payable.

Annual (Calendar Year) Net Sales of all Elected Unilateral Adaptimmune Products	Sales Milestone Payment Amount
[***]	[***]
[***]	[***]
[***]	[***]
Total sales milestones payable	[***]

11.2.5 Notices; Further Clarification. A Party shall promptly notify and invoice the other Party of the occurrence of each development and regulatory milestone or sales milestones for the applicable Product as set forth in Section 11.2.1 (Development and Regulatory Milestones Payable to Adaptimmune), Section 11.2.2 (Development and Regulatory Milestones Payable to Universal Cells), Section 11.2.3 (Sales Milestones Payable to Adaptimmune), and Section 11.2.4 (Sales Milestones Payable to Universal Cells), and the Party obligated to pay such milestone payment shall pay the Party to whom such milestone payment is due within twenty (20) days of provision of such notice and invoice. Such milestone payments shall be non-refundable and shall not be credited against royalties payable to Adaptimmune under this Agreement. If a given Product for which a milestone as set forth in Section 11.2 (Milestone Payments) applies is developed for additional indications, and a given milestone payment has previously been made for such Product, no additional milestones shall be paid with respect to the achievement of such milestone for such additional indications for the same Product.

**11.3 Collaboration Profit-Share Products.** Universal Cells and Adaptimmune will equally share Development Costs, Program Costs and Profits (each as defined in <u>Schedule 11.3</u>) <u>arising</u> from the Development, Manufacture and Commercialization of Collaboration Profit-Share Products worldwide. <u>Schedule 11.3</u> specifies the calculation of such costs and Profits and provides for the manner in which Universal Cells will pay Adaptimmune its share of Profits, and the manner in which the Parties will reconcile and pay their equal allocations of Development Costs and other Program Costs.

#### 11.4 Royalties.

11.4.1 Unilateral Universal Cells Products. Universal Cells shall make quarterly non-refundable royalty payments to Adaptimmune on the total Net Sales of all Unilateral Universal Cells Products sold in the Territory by Universal Cells, its Affiliates, and its sublicensees, as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated annual Net Sales of all Unilateral Universal Cells Products (cumulatively) sold in the Territory by Universal Cells, its Affiliates, and its sublicensees in the applicable Calendar Quarter. Universal Cells' obligation to pay royalties under this Section 11.4.1 (Unilateral Universal Cells Products) shall expire upon expiration of the Unilateral Universal Cells Product Royalty Term on a per-Unilateral Universal Cells Product and per-country basis.

For that portion of annual (Calendar Year) Net Sale of all Unilateral Universal Cells Product in the Territory by Universal Cells and its Affiliates and sublicensees	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

11.4.2 Elected Universal Cells Program Products. Universal Cells shall make quarterly non-refundable royalty payments to Adaptimmune on the Net Sales of all Elected Universal Cells Program Products sold in the Territory by Universal Cells, its Affiliates, and its sublicensees, as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated annual Net Sales of all Elected Universal Cells Program Products (cumulatively) sold in the Territory by Universal Cells, its Affiliates, and its sublicensees in the applicable Calendar Quarter. Universal Cells' obligation to pay royalties under this Section 11.4.2 shall expire upon expiration of the Elected Universal Cells Program Product Royalty Term on a per-Elected Universal Cells Program Product and per-country basis.

For that portion of annual (Calendar Year) Net Sale of all Elected Universal Cells Program Product in the Territory by Universal Cells and its Affiliates and sublicensees	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

11.4.3 Certain Elected Unilateral Adaptimmune Products. Adaptimmune shall make quarterly non-refundable royalty payments to Universal Cells on the Net Sales of all Elected Unilateral Adaptimmune Products sold in the Territory by Adaptimmune, its Affiliates, and its sublicensees, as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated annual Net Sales of all Elected Unilateral Adaptimmune Product (cumulatively) sold in the Territory by Adaptimmune, its Affiliates, and its sublicensees in the applicable Calendar Quarter but only for Elected Unilateral Adaptimmune Products where (a) the Elected Unilateral Adaptimmune Product incorporates or is derived from Contributed Technology in accordance with Section 3.5 (Contributed Technology) and (c) Universal Cells has granted Adaptimmune an Elected Unilateral Adaptimmune Product License in accordance with Section 9.2.1 (Unilateral Adaptimmune Product Elected License). For all other Elected Unilateral Adaptimmune Products (e.g. one containing such a Receptor that is *not* covered by a Valid Claim of any Patent Right Controlled by Universal Cells or its Affiliates), no royalties under this Section 11.4.3 (Certain Elected Unilateral Adaptimmune Products) shall be payable, and instead the royalties set forth in Section 11.4.5 (Other Unilateral Adaptimmune Products) will apply. Adaptimmune's obligation to pay royalties under this Section 11.4.3 shall expire upon expiration of the Elected Unilateral Adaptimmune Product Royalty Term on a per Elected Unilateral Adaptimmune Product and per-country basis.

For that portion of annual Net Sale of all Elected Unilateral Adaptimmune Product in the Territory by Adaptimmune and its Affiliates and sublicensees	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

**11.4.4 Other Universal Cells Program Product**. Universal Cells shall make a quarterly non-refundable royalty payments to Adaptimmune equal to [\*\*\*] of the Net Sales of Other Universal Cells Program Products sold in the Territory by Universal Cells, its Affiliates, and its sublicensees in such Calendar Quarter.

**11.4.5 Other Unilateral Adaptimmune Products**. Adaptimmune shall make a quarterly non-refundable royalty payments to Universal Cells equal to [\*\*\*] of the Net Sales of all Unilateral Adaptimmune Products (cumulatively) sold in the Territory by Adaptimmune, its Affiliates, and its sublicensees in such Calendar Quarter other than Elected Unilateral Adaptimmune Products for which a royalty is payable pursuant to Section 11.4.3 (Certain Elected Unilateral Adaptimmune Products).

## 11.4.6 Royalty Reductions and Floor.

- (a) **No Valid Claims**. Subject to Section 11.4.6(c) (Royalty Reductions Floor), on a Product-by-Product and country-by-country basis, the royalties payable pursuant to Section 11.4.1 (Unilateral Universal Cells Products) and Section 11.4.2 (Elected Universal Cells Program Products) by a Party with respect to the Net Sales of a Product in a country will be reduced by [\*\*\*] during each Calendar Quarter in which there exists no Valid Claim within the Patent Rights exclusively licensed to such Party under this Agreement that covers such Product or the making, using, or selling thereof in such country. In addition, subject to Section 11.4.6(c) (Royalty Reductions Floor), on a Product-by-Product and country-by-country basis, the royalties payable pursuant to Section 11.4.3 (Certain Elected Unilateral Adaptimmune Products) by a Adaptimmune with respect to the Net Sales of an Elected Unilateral Adaptimmune Product in a country in will be reduced [\*\*\*] during each Calendar Quarter in which there exists no Valid Claim within the Patent Rights exclusively licensed to Adaptimmune under the Elected Unilateral Adaptimmune Product License or from which such Elected Unilateral Adaptimmune Product was derived.
  - (b) Anti-Royalty Stacking. [\*\*\*].
  - (c) [\*\*\*].
- **11.5 Royalty Reports; Payments.** Within [\*\*\*] after the end of each Calendar Quarter in which a Party required to pay royalties to the other Party with respect to Net Sales of Products as specified in Section 11.4 (Royalties), such Party shall submit to the other Party a report, on the basis of each Product and country, providing in reasonable detail an accounting of all Net Sales of the relevant royalty-bearing Products made during such Calendar Quarter and the calculation of the applicable royalty under Section 11.4 (Royalties). Within [\*\*\*] of such report, the royalty-paying Party submitting the report shall pay to the other Party all royalties payable by it under Section 11.4 (Royalties), as indicated in the report.

under this Agreement for a period of [\*\*\*] years after the end of the Calendar Year in which any such payment was due. Each Party will have the right, once annually at its own expense, to have a nationally recognized, independent, certified public accounting firm, selected by it and subject to the other Party's prior written consent (which shall not be unreasonably withheld, conditioned or delayed), review any such records of the other Party and its Affiliates (the "Audited Party") in the location(s) where such records are maintained by the Audited Party upon reasonable written notice (which shall be no less than [\*\*\*] days' prior written notice) and during regular business hours and under obligations of strict confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement within [\*\*\*] year period preceding the date of the request for review. Each Party shall require its sublicensees to retain and provide to such Party all records of payments that such Party would be required to keep as if sales of a given Product by such sublicensees were sales of Product by such Party, to enable the other Party to audit such records pursuant to this Section 11.6. No Calendar Year will be subject to audit under this Section 11.6 more than once. The Audited Party will receive a copy of each such report concurrently with receipt by the non-Audited Party, and such accounting firm shall report to the Parties only whether or not such calculations are correct and the amount of any discrepancy. No other information shall be shared. Each Party agrees to treat the results of any such review of the other Party's records under this Section 11.6 as Confidential Information of the other Party and subject to the terms of Article 11 (Financial Provisions). Should such inspection lead to the discovery of a discrepancy to the non-Audited Party's detriment, the Audited Party will, within [\*\*\*] days after receipt of such report from the accounting firm, pay any undisputed amount of the discrepancy. Each Party requesting review under this Section 11.6 will pay the full cost of the review unless the underpayment of amounts due to the non-Audited Party is greater than [\*\*\*] of the amount due for the entire period being examined, in which case the Audited Party will pay the reasonable cost charged by such accounting firm for such review. Should the audit lead to the discovery of a discrepancy to the Audited Party's detriment, the Audited Party may, at its option, credit the amount of the discrepancy, without interest, against future payments payable to the non-Audited Party under this Agreement, and if there are no such payments payable or if the Audited Party elects not to apply such credit, then non-Audited Party shall pay to the Audited Party the amount of the discrepancy, plus interest in accordance with Section 11.8 (Late Payments), within thirty (30) days of non-Audited Party's receipt of the report.

11.6

Records and Audits. Each Party will keep complete and accurate records of payments required

11.7 Currency Exchange. With respect to Net Sales invoiced or expenses incurred in U.S. dollars, the Net Sales or expense amounts and the amounts due to the receiving Party hereunder shall be expressed in U.S. dollars. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. dollars, the Net Sales or expense shall be expressed in the domestic currency of the entity making the sale or incurring the expense, together with the U.S. dollar equivalent, calculated using the arithmetic average of the spot rates on the last business day of each month of the calendar quarter in which the Net Sales were made or the expense was incurred. The "closing mid-point rates" found in the "dollar spot forward against the dollar" table published by the Financial Times or any other publication as agreed to by the Parties shall be used as the source of spot rates to calculate the average as defined in the preceding sentence. All payments shall be made in U.S. dollars. If at any time legal restrictions in any country in the Territory prevent the prompt remittance of any payments with respect to sales in that country, the paying Party shall have the right and option to make such payments by depositing the amount thereof in local currency to the receiving Party's account in a bank or depository in such country.

**11.8 Late Payments.** The paying Party shall pay interest to the receiving Party on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to [\*\*\*], or the highest rate permitted by Applicable Law, calculated on the number of days such payments are paid after the date such payments are due.

### 11.9 Taxes.

11.9.1 Withholding. In the event that any Applicable Law requires the Party obligated to make a payment to the other Party hereunder ("Paying Party") to withhold taxes with respect to any payment to be made by the Paying Party pursuant to this Agreement, the Paying Party (a) will notify the non-Paying Party of such withholding requirement prior to making the payment to the non-Paying Party (such notice, which shall include the authority, basis and method of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for such non-Paying Party to obtain reduction of or relief from such deduction or withholding), and (b) provide such assistance to the non-Paying Party, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in the non-Paying Party's efforts to claim an exemption from or reduction of such taxes. The Paying Party will, in accordance with Applicable Law, withhold taxes from such payment, remit such taxes to the appropriate tax authority, and furnish the non-Paying Party with proof of payment of such taxes within thirty (30) days following the payment. If taxes are so withheld and paid to a tax authority, the Paying Party shall provide reasonable assistance to the non-Paying Party to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. If any taxes are so withheld and paid to the appropriate tax authority in accordance with this Section 11.9.1, such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the non-Paying Party. The non-Paying Party shall provide the Paying Party any tax forms (including Internal Revenue Service Forms W-9 or applicable W-8) that may be reasonably necessary in order for the Paying Party to determine whether to withhold tax on any such payments or to withhold tax on such payments at a reduced rate under Applicable Law, including any applicable bilateral income tax treaty.

11.9.2 Indirect Taxes. All payments due to the non-Paying Party from the Paying Party pursuant to this Agreement shall be paid exclusive of any value-added tax, sales tax, consumption taxes and other similar taxes ("Indirect Taxes") (which, if applicable, shall be payable by the Paying Party upon receipt of a valid Indirect Tax invoice). If the non-Paying Party determines that it is required to report any such tax, the Paying Party shall promptly provide the non-Paying Party with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section 11.9.2 is not intended to limit the Paying Party's right to deduct value-added taxes in determining Net Sales.

## **ARTICLE 12**

#### CONFIDENTIALITY

**12.1 Confidential Information**. A Party receiving Confidential Information from a disclosing Party will keep all of the disclosing Party's Confidential Information in confidence with the same degree of care with which the receiving Party holds its own Confidential Information

(but in no event less than a commercially reasonable degree of care). The receiving Party will not use the disclosing Party's Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. The receiving Party may disclose the disclosing Party's Confidential Information without the disclosing Party's prior written consent solely to the receiving Party's Affiliates and their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are bound by restrictions on use and disclosure consistent with this Article 12 (Confidentiality) and to sublicensees who are granted a sublicense to such information in accordance with this Agreement. The receiving Party assumes responsibility for those entities and persons maintaining the disclosing Party's Confidential Information in confidence and using same only for the purposes described herein. With respect to Confidential Information that is Know-How generated in the course of performing activities under the Collaboration or with respect to Unilateral Products, the owner of such Know-How pursuant to Section 9.7 (Ownership of Arising Inventions and Intellectual Property Rights) will be deemed to be the discloser of such Confidential Information and the other Party will be deemed to the recipient thereof, and where the Parties are joint owners of Confidential Information, each Party will be deemed to be both the discloser and recipient of such Confidential Information. Notwithstanding the foregoing, clinical and nonclinical data generated in the performance of clinical trials or nonclinical or pre-clinical studies of a Unilateral Product will belong to the Party who is responsible for such Unilateral Product (i.e., Adaptimmune for Unilateral Adaptimmune Products and Universal Cells for Unilateral Universal Cells Products), and such Party will be deemed to be the discloser of such data and the other Party the recipient. The Parties will jointly own, and each Party will be deemed to be both the discloser and recipient of, clinical and nonclinical data generated in the performance of clinical trials or nonclinical or pre-clinical studies of Collaboration Products.

- **12.2 Exceptions.** The following information will not be Confidential Information for purposes of this Agreement and accordingly the terms of this Article 12 (Confidentiality) and the receiving Party's obligation of nondisclosure and non-use as set forth in this Article 12 (Confidentiality) will not apply to such information that the receiving Party can demonstrate with competent proof:
- **12.2.1** was known by the receiving Party or its Affiliates prior to its date of first disclosure to the receiving Party; or
- **12.2.2** was lawfully disclosed to the receiving Party or its Affiliates by sources other than the disclosing Party without breach of an obligation of confidentiality; or
- **12.2.3** is or becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Affiliates or its sublicensees; or
- **12.2.4** is independently developed by or for the receiving Party or its Affiliates without reference to or reliance upon the Confidential Information as shown by written files or records.
- **12.3 Permitted Disclosure**. Notwithstanding the restrictions imposed in Section 12.2 (Exceptions), the receiving Party may disclose the disclosing Party's Confidential Information to

the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

- **12.3.1** in order to comply with Applicable Law (including any securities law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;
- **12.3.2** in connection with prosecuting and defending litigation, seeking Regulatory Approvals for Products and in making other filings, submissions, and communications with Regulatory Authorities related to any Products, and, solely with the prior written consent of the disclosing Party (not to be unreasonably withheld, conditioned, or delayed) filing, prosecuting, and enforcing Patent Rights solely in connection with exercising the receiving Party's rights and fulfilling the receiving Party's obligations pursuant to this Agreement; and
- **12.3.3** to actual or bona fide potential collaborators (including sublicensees), acquirers or assignees, investment bankers, investors, lenders, and other advisors;

provided, however, that (a) with respect to Sections 12.3.1 or 12.3.2 where reasonably possible, the receiving Party will notify the disclosing Party of receiving Party's intent to make any disclosure pursuant prior to making such disclosure so as to allow disclosing Party to protect the confidentiality of the information to be disclosed (and the receiving Party shall reasonably assist the disclosing Party upon request in taking such actions); and (b) with respect to Section 12.3.3, each of those named people and entities are bound by restrictions on use and disclosure consistent with Article 12 (Confidentiality) (other than investment bankers, investors, lenders, and other advisors, who must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

- **12.4 Terms of this Agreement; Publicity**. The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 12.3 (Permitted Disclosure). Except as required by Applicable Law or as permitted under Section 12.3 (Permitted Disclosure), each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed (provided that with respect to the content of a statement previously made in accordance with this Section 12.4, a Party shall not require the consent of the other Party to disclose such content in a future statement or press release so long as such information remains accurate and up-to-date). Notwithstanding the foregoing, a press release in the form attached hereto as <u>Schedule 12.4</u> shall be issued by the Parties on or as promptly as practicable after the Effective Date.
- **12.5 Duration of Obligations**. All obligations of confidentiality and non-use imposed under this Article 12 (Confidentiality) shall expire [\*\*\*].

#### 12.6 Publications.

**12.6.1 Universal Cells Publication Rights.** Universal Cells will have the sole right to publish and make scientific presentations with respect to Collaboration Products, Collaboration Profit-Share Products, Universal Cells Program Products, and Unilateral Universal Cells Products, and to issue press releases (except with respect to the terms of this Agreement,

which is governed by Section 12.4 (Terms of this Agreements; Publicity)) or make other public disclosures regarding any such Collaboration Products, Collaboration Profit-Share Products, Universal Cells Program Products, and Unilateral Universal Cells Products, consistent with <u>Schedule 2.4.2</u>. Adaptimmune will not issue any such publications without Universal Cells' prior written consent, except as required by Applicable Law. Notwithstanding the foregoing, any such publication or presentation to be made by Universal Cells that names Adaptimmune will require the prior written consent of Adaptimmune.

**12.6.2 Adaptimmune Publication Rights.** Adaptimmune will have the sole right to publish and make scientific presentations with respect to the Adaptimmune Technology and Unilateral Adaptimmune Products, and to issue press releases (except with respect to the terms of this Agreement, which is governed by Section 12.4 (Terms of this Agreements; Publicity)) and to make other public disclosures regarding any such Adaptimmune Technology and Unilateral Adaptimmune Products consistent with Adaptimmune's publication policy. Universal Cells will not issue any such publications without Adaptimmune's prior written consent, except as required by Applicable Law. Notwithstanding the foregoing, any such publication or presentation to be made by Adaptimmune that names Universal Cells will require the prior written consent of Universal Cells.

12.6.3 Publication Procedures. The Party that is entitled under Section 12.6 (Publications) to make a publication or presentation (the "Publishing Party") will deliver to the other Party (the "Non-Publishing Party") a copy of the proposed written publication or outline of presentation to be made by the Publishing Party at least thirty (30) days in advance of submission (or, where a copy of such publication or presentation is not available at such time, a draft or outline of such publication or a description of such presentation), and the Non-Publishing Party will have the right to: (a) require a delay of submission of not more than sixty (60) days to enable the filing of patent applications with information from such proposed publication or presentation in accordance with this Agreement; and (b) prohibit disclosure of any of the Non-Publishing Party's Confidential Information in any such proposed publication or presentation. If the Non-Publishing Party has not provided any comments or otherwise exercised its rights as described in this Section 12.6.3 within thirty (30) days of receiving a copy of such proposed written publication or outline of presentation, the Publishing Party shall be free to submit such publication or to orally disclose or publish the disclosed information in a manner consistent with Schedule 2.4.2.

#### **ARTICLE 13**

#### **TERM AND TERMINATION**

**13.1 Term**. This Agreement becomes effective as of the Effective Date and shall expire on a Product-by-Product and country-by-country basis upon the expiration of (a) with respect to Collaboration Profit-Share Products, both Parties' payment obligations to the other Party hereunder, and (b) with respect to other Products, the applicable royalty term for a Product in a country, unless terminated earlier in accordance herewith (the "**Term**").

## 13.1.1 Effects of Expiration of Royalty Terms.

- (a) **Elected Unilateral Adaptimmune Product**. Upon the expiration of the Elected Unilateral Adaptimmune Product Royalty Term with respect to a given Elected Unilateral Adaptimmune Product in a given country, the licenses granted under this Agreement to exploit such Elected Unilateral Adaptimmune Product in such country shall become fully-paid, irrevocable, and non-exclusive.
- (b) **Other Unilateral Adaptimmune Product**. Upon the expiration of the Other Unilateral Adaptimmune Product Royalty Term with respect to a given Other Unilateral Adaptimmune Product in a given country, the licenses granted under this Agreement to exploit such Other Unilateral Adaptimmune Product in such country shall become fully-paid, irrevocable, and non-exclusive.
- (c) **Elected Universal Cells Program Product**. Upon the expiration of the Elected Universal Cells Program Product Royalty Term with respect to a given Elected Universal Cells Program Product in a given country, the licenses granted under this Agreement to exploit such Elected Universal Cells Program Product in such country shall become fully-paid, irrevocable, and non-exclusive.
- (d) **Other Universal Cells Program Product**. Upon the expiration of the Other Universal Cells Program Product Royalty Term with respect to a given Other Universal Cells Program Product in a given country, the licenses granted under this Agreement to exploit such Other Universal Cells Program Product in such country shall become fully-paid, irrevocable, and non-exclusive.
- (e) **Unilateral Universal Cells Product.** Upon the expiration of the Unilateral Universal Cells Product Royalty Term with respect to a given Unilateral Universal Cells Product in a given country, the licenses granted under this Agreement to exploit such Unilateral Universal Cells Product in such country shall become fully-paid, irrevocable, and non-exclusive.

## 13.2 Termination By Universal Cells.

## 13.2.1 Adaptimmune Breach.

(a) **All Targets**. Universal Cells will have the right to terminate this Agreement in its entirety in the event of any material breach by Adaptimmune of this Agreement that frustrates the fundamental purpose of this Agreement; *provided*, *however*, that such termination will not be effective if such breach has been cured within [\*\*\*] after written notice thereof is given by Universal Cells to Adaptimmune specifying the nature of the alleged breach; *provided*, *further*, *however*, if such breach is not reasonably subject to cure within [\*\*\*] after receipt of written notice thereof, then Adaptimmune shall have an additional [\*\*\*] (or such longer period as may be agreed by the Parties in writing) to effect such cure provided that Adaptimmune is undertaking reasonable efforts to cure such breach during such additional [\*\*\*] period and has provided to Universal Cells a written plan intended to cure such breach within such additional period. Notwithstanding the foregoing in this Section 13.2.1 (Adaptimmune Breach), in the event of a good faith dispute as to whether a material breach by Adaptimmune has occurred, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute

in accordance with the terms of this Agreement; *provided*, *however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

(b) **Target-Specific**. Universal Cells will have the right to terminate this Agreement with respect to a given Product Directed To a given Target in the event of any material breach by Adaptimmune of this Agreement that relates only to such Product Directed To such Target; *provided*, *however*, that such termination will not be effective if such breach has been cured within [\*\*\*] after written notice thereof is given by Universal Cells to Adaptimmune specifying the nature of the alleged breach; *provided*, *further*, *however*, if such breach is not reasonably subject to cure within [\*\*\*] after receipt of written notice thereof, then Adaptimmune shall have an additional [\*\*\*] to effect such cure provided that Adaptimmune is undertaking reasonable efforts to cure such breach during such additional [\*\*\*] period and has provided to Universal Cells a written plan intended to cure such breach within such additional period. Notwithstanding the foregoing in this Section 13.2.1 (Adaptimmune Breach), in the event of a good faith dispute as to whether a material breach by Adaptimmune has occurred, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided*, *however*, if such dispute relates to payment, such tolling of the cure period will only apply with respect to payment of the disputed amounts, and not with respect to any undisputed amount.

### 13.2.2 Termination for Convenience.

- (a) **All Targets**. Universal Cells may terminate this Agreement at will in its entirety (i) prior to commencement of any clinical trial for any Collaboration Product, with [\*\*\*] advance written notice to Adaptimmune or (ii) following the commencement of any clinical trial for a Collaboration Product, with [\*\*\*] advance written notice to Adaptimmune.
- (b) **Collaboration Products**. Universal Cells may terminate this Agreement at will with respect to one or more Collaboration Target(s), and the Collaboration Product(s) Directed To such Collaboration Target(s) (i) prior to commencement of any clinical trial for any Collaboration Product Directed To such Collaboration Target, with [\*\*\*] advance written notice to Adaptimmune or (ii) following the commencement of any clinical trial for a Collaboration Product Directed To such Collaboration Target, effective upon [\*\*\*] days following the date of written notice to Adaptimmune.
- (c) Conversion to Unilateral Adaptimmune Target and Product. In the event of receipt of notice of termination of this Agreement from Universal Cells with respect to one or more Collaboration Targets pursuant to this Section 13.2.2, Adaptimmune will have the right to elect, within [\*\*\*] of receipt of such notice of termination to designate such terminated Collaboration Targets as Unilateral Adaptimmune Targets for purposes of this Agreement, in which case, the Collaboration Product Directed To such Target will thereafter be Unilateral Adaptimmune Products and Section 13.5.3 (Transition from Collaboration Product to Unilateral Product) shall apply with respect to such transition of such Collaboration target and Collaboration Product to Unilateral Adaptimmune Target and Unilateral Adaptimmune Product.

- (d) **Universal Cells Program Products**. Universal Cells may terminate this Agreement at will with respect to a Universal Cells Program Target and the Universal Cells Program Product Directed To such Universal Cell Program Target with ninety (90) days' advance written notice to Adaptimmune.
- (e) **Unilateral Universal Cells Products**. Universal Cells may terminate this Agreement at will with respect to one or more Unilateral Universal Cells Target and the Unilateral Universal Cells Product Directed To such Universal Cell Program Target effective upon ninety (90) days following the date of written notice to Adaptimmune.

## 13.3 Termination by Adaptimmune.

#### 13.3.1 Universal Cells Breach.

- (a) **All Targets.** Adaptimmune will have the right to terminate this Agreement in its entirety in the event of any material breach by Universal Cells of this Agreement that frustrates the fundamental purpose of this Agreement; *provided*, *however*, that such termination will not be effective if such breach has been cured within [\*\*\*] after written notice thereof is given by Adaptimmune to Universal Cells specifying the nature of the alleged breach; *provided*, *further*, however, if such breach is not reasonably subject to cure within [\*\*\*] after receipt of written notice thereof, then Universal Cells shall have an additional [\*\*\*] to effect such cure provided that Universal Cells is undertaking reasonable efforts to cure such breach during such additional [\*\*\*] period and has provided to Adaptimmune a written plan intended to cure such breach within such additional period. Notwithstanding the foregoing in this Section 13.3.1, in the event of a good faith dispute as to whether a material breach by Universal Cells has occurred, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided*, *however*, if such dispute relates to payment, then such tolling of the cure period will only apply with respect to payment of the disputed amounts and not with respect to any undisputed amount.
- (b) **Target-Specific.** Adaptimmune will have the right to terminate this Agreement with respect to a given Product Directed To a given Target in the event of any material breach by Universal Cells of this Agreement that relates only to such Product Directed To such Target; provided, however, that such termination will not be effective if such breach has been cured within [\*\*\*] after written notice thereof is given by Adaptimmune to Universal Cells specifying the nature of the alleged breach; *provided*, *further*, *however*, if such breach is not reasonably subject to cure within [\*\*\*] after receipt of written notice thereof, then Universal Cells shall have an additional [\*\*\*] to effect such cure if Universal Cells is undertaking reasonable efforts to cure such breach during such additional [\*\*\*] period and has provided to Adaptimmune a written plan intended to cure such breach within such additional period. Notwithstanding the foregoing in this Section 13.3.1, in the event of a good faith dispute as to whether a material breach by Universal Cells has occurred, the foregoing cure period with respect thereto will be tolled pending final resolution of such dispute in accordance with the terms of this Agreement; *provided*, *however*, if such dispute relates to payment, then such tolling of the cure period will only apply with respect to payment of the disputed amounts and not with respect to any undisputed amount.

- **13.3.2 Termination for Convenience for Unilateral Adaptimmune Targets.** Adaptimmune may terminate this Agreement at will with respect to one or more Unilateral Adaptimmune Target, and the Unilateral Adaptimmune Product Directed To such Unilateral Adaptimmune Target(s) effective upon [\*\*\*] following the date of written notice to Universal Cells.
- **13.4 Effects of Termination Generally**. Upon termination by a Party, as applicable, under Section 13.2 (Termination By Universal Cells) or Section 13.3 (Termination by Adaptimmune) (or, to the extent this Agreement is terminated solely with respect to a particular Target then the remainder of this Section 13.4 (Effects of Termination Generally) shall only apply to the terminated Target and the Product Directed To such terminated Target), the following shall apply, except as provided in Section 13.5 (Effects of Termination with Respect to Collaboration Targets):
- **13.4.1 Ongoing Clinical Studies**. The Parties will responsibly wind-down, in accordance with accepted biopharmaceutical industry norms and ethical practices, any on-going clinical studies terminated Product Directed To a terminated Target for which they respectively have responsibility hereunder in which patient dosing has commenced, and the terminating Party will be responsible for any costs associated with such wind-down or transition.
- **13.4.2 Termination of Licenses**. All licenses and sublicenses granted under this Agreement with respect to the terminated Target and terminated Product Directed To such terminated Target, as of the effective date of such termination, shall terminate automatically unless otherwise agreed by the Parties.
- 13.4.3 Destruction of Confidential Information. Each Party that has received Confidential Information of the other Party related to the terminated Target(s) or terminated Product Directed To such Target(s) shall destroy (at such Party's written request) all such Confidential Information (including for clarity all cell lines and other materials of the other Party) in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement), and any Confidential Information of the other Party contained in its laboratory notebooks or databases, *provided* that each Party may retain and continue to use such Confidential Information of the other Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Notwithstanding the foregoing, a Party shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its employees, consultants, or others who received Confidential Information under this Agreement.

## 13.5 Effect of Termination With Respect to Collaboration Targets.

**13.5.1 Termination by Universal Cells for Convenience or by Adaptimmune for Breach.** Upon termination by Universal Cells pursuant to Section 13.2.2 (Termination for Convenience) or termination by Adaptimmune pursuant to Section 13.3.1 (Universal Cells Breach) of this Agreement in its entirety or solely with respect to one or more

Collaboration Target(s) (and each Collaboration Product Directed To such terminated Collaboration Target(s)):

- (a) all rights and licenses granted to Universal Cells under this Agreement shall terminate with respect to the terminated Collaboration Target(s) (and each Collaboration Product Directed To such terminated Collaboration Target(s)); and
- (b) all rights and licenses granted to Adaptimmune under this Agreement shall survive with respect to all terminated Collaboration Target(s) (and each Collaboration Product Directed To such Collaboration Target) and such Collaboration Target(s) and each Collaboration Product Directed To such Collaboration Target shall become Unilateral Adaptimmune Target(s) and Unilateral Adaptimmune Products, respectively, subject to the royalty payment obligations applicable to Unilateral Adaptimmune Products pursuant to Section 11.4 (Royalties).
- **13.5.2 Termination by Universal Cells for Breach**. Upon termination by Universal Cells pursuant to Section 13.2.1 (Adaptimmune Breach) of this Agreement in its entirety or solely with respect to one or more Collaboration Target(s) (and each Collaboration Product Directed To such terminated Collaboration Target(s)):
- (a) all rights and licenses granted to Adaptimmune under this Agreement shall terminate with respect to the terminated Collaboration Target(s) (and each Collaboration Product Directed To such terminated Collaboration Target(s)); and
- (b) all rights and licenses granted to Universal Cells under this Agreement shall survive with respect to all terminated Collaboration Target(s) (and each Collaboration Product Directed To such Collaboration Target) and such Collaboration Target(s) and each Collaboration Product Directed To such Collaboration Target shall become Unilateral Universal Cells Target(s) and Unilateral Universal Cells Products, respectively, subject to the royalty payment obligations applicable to Unilateral Universal Cells Products pursuant to Section 11.4 (Royalties)
- 13.5.3 Transition from Collaboration Product to Unilateral Product. In the event a Collaboration Target and the Collaboration Product Directed To such Collaboration Target becomes a Unilateral Target and Unilateral Product in accordance with Section 4.10.3 (Unilateral Products and Targets), Section 13.2.2(c) (Conversion to Unilateral Adaptimmune Target and Product), 13.5.2(b) (Termination by Universal Cells for Breach), or Section 17.2.3(d) (Collaboration Research Program Products), the Party that is continuing to Develop, Manufacture, Commercialize, and otherwise exploit such Product as a Unilateral Product shall be the "Continuing Party" and the other Party shall be the "Ceasing Party". In connection with such transition of such Collaboration Product to a Unilateral product:

[\*\*\*].

**13.6 Survival**. The termination of this Agreement shall not relieve Universal or Adaptimmune from performing any obligations accrued prior to the date this Agreement terminates or any obligations which are expressed to survive termination of this Agreement including Article 1 (to the extent required for interpretation of other Sections and Clauses surviving

termination), Section 9.1 (solely as and to the extent specified in this Agreement, and as may be modified as set forth herein), Section 9.7, Sections 10.1.3 and 10.1.4 (in the event of termination of this Agreement, for the duration as specified therein), Article 11 (for any payments accrued but not yet paid as of termination, and for any payment obligations set forth in the agreement that apply after any such termination), Sections 12.1-12.4 (for the duration specified in Section 12.5), Article 13, Article 14, Article 16 (as to activities conducted during the Term and during a party's practice of a license granted under this agreement thereafter) and Article 17 (and with respect to Section 17.7, for the duration specified therein).

#### **ARTICLE 14**

#### **DISPUTE RESOLUTION**

- 14.1 Referral Of Unresolved Matters to Executive Officers. Except with respect to matters for which a Party has unilateral decision-making authority as expressly specified hereunder and any matter within the decision-making authority of the JSC as set forth herein (except for the Executive Resolution Matters, which shall be referred to the Executive Officers as set forth in Section 2.2.4 (Decision Making) and not subject to this Section 14.1), a disputed matter shall be referred to the Executive Officers to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. Such resolution, if any, of a matter referred by the Executive Officers shall be final and binding on the Parties.
- **14.2 Arbitration**. If a dispute is not resolved as stated in Section 14.1 (Referral Of Unresolved Matters to Executive Officers), then either Party may, by written notice, submit any dispute to binding arbitration, which shall take place pursuant to the procedures set forth in this Section 14.2 (Arbitration).
- **14.2.1 Rules**. The Parties agree that, except as otherwise set forth in Section 14.1 (Referral Of Unresolved Matters to Executive Officers) or Section 14.2.11 (Exception), any dispute, controversy, or claim arising out of or relating to this Agreement, or the breach, termination, or invalidity thereof, shall be finally resolved by binding arbitration administered by the American Arbitration Association in accordance with the then current Commercial Arbitration Rules (the "**Rules**"), except as modified herein.
- **14.2.2 Arbitrators**. Each Party shall select one arbitrator and the two arbitrators so selected shall choose a third arbitrator. All three arbitrators shall serve as neutrals and have at least ten years of: (a) dispute resolution experience (including judicial experience); or (b) legal or business experience in the biopharmaceutical industry. In any event, at least one arbitrator shall satisfy the foregoing experience requirement under clause (b). If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator, the necessary appointments shall be made in accordance with the Rules. Once an arbitrator is appointed, neither Party shall have any *ex parte* communication with such arbitrator.
- **14.2.3 Location**. The arbitration proceedings shall be conducted in New York, NY, or such other location as may be agreed in writing by the Parties.

- **14.2.4 Language**. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof.
- **14.2.5 Making Employees Available**. Each Party agrees to use reasonable efforts to make all of its then current employees available, if reasonably needed, and agrees that the arbitrators may deem any Person as "necessary."
- **14.2.6 Duration**. The arbitration shall be concluded within six (6) months following the filing of the initial request for arbitration, unless the Parties agree in writing to extend the duration.
- 14.2.7 Award. The arbitrators shall be instructed and required to render a final written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than ninety (90) days after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. The arbitrators will not have authority to: (a) make any award that could not be made by a court of competent jurisdiction; or (b) modify the limitations on liability set forth herein or make any award in violation thereof. Each Party agrees that, notwithstanding any provision of Applicable Law or of this Agreement, except as permitted under Section 16.5 (Limitation of Liability), it will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against any Party.
- **14.2.8 Fees and Costs**. The Party that the arbitrators deem to be the prevailing Party shall be entitled to all fees and costs, unless the arbitrators, in their discretion, determine that the Parties shall: (a) share equally the fees and expenses of the arbitrators; and (b) bear their own attorneys' fees and associated costs and expenses otherwise.
- **14.2.9 Confidentiality**. All proceedings and decisions of the arbitral tribunal in connection with an arbitral proceeding pursuant to this Section 14.2 (Arbitration) shall be deemed Confidential Information of each of the Parties and shall be subject to Article 12 (Confidentiality) except to the extent necessary to confirm an award or as may be required by Applicable Law.
- **14.2.10 Injunctive Relief.** Notwithstanding anything to the contrary set forth in this Article 14 (Dispute Resolution), a Party shall not be required to use the foregoing dispute resolution procedures or otherwise follow the provisions of this Section 14.2 (Arbitration) with respect to any dispute to which a Party is seeking purely injunctive or other equitable, non-monetary relief and such Party shall be entitled to seek relief before any court having jurisdiction over such dispute and the Parties hereto. In addition, the Parties may apply to any court of competent jurisdiction for interim relief (including for breaches or threatened breaches with respect to Confidential Information), as necessary, without being subject to these arbitration provisions and without abridging the powers of the arbitrators.

**14.2.11 Exception**. Notwithstanding anything to the contrary in this Section 14.2 (Arbitration), any disputes regarding the inventorship, enforceability, validity or scope of patent rights shall be resolved by a court of competent jurisdiction and not submitted for resolution by arbitration.

### **ARTICLE 15**

#### REPRESENTATIONS, WARRANTIES AND COVENANTS

- **15.1 Adaptimmune**. Adaptimmune represents, warrants, and covenants to Universal Cells as of the Effective Date that:
- **15.1.1 Ownership Of Intellectual Property**. Except as set forth in <u>Schedule 15.1.1</u>, Adaptimmune is the sole legal and beneficial owner of the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement and to its knowledge Adaptimmune has obtained written assignments of all right, title, and interest from inventors of such Adaptimmune Background IP.
- **15.1.2 Inventorship**. It is not aware of any Third Party who has made an inventive contribution to any of the inventions disclosed and claimed in the Patent Rights within the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement, other than those inventors named as inventors in such Patent Rights.
- **15.1.3 Prosecution and Maintenance**. It has complied with all Applicable Laws in all material respects, including any disclosure requirements, in connection with the filing, prosecution, and maintenance of the Patent Rights within the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement.
- **15.1.4 Misappropriation**. To its knowledge, the conception, development, and reduction to practice of the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement has not constituted nor involved the misappropriation of trade secrets or other rights or property of any Third Party.
- **15.1.5 Knowledge Of Pending Or Threatened IP Challenge**. It is not aware of any claim made against it asserting the invalidity, misuse, unregisterability, unenforceability, or non-infringement of any Patent Right within the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement, or challenging its right to use or ownership thereof, or making any adverse claim of ownership thereof, and it has no knowledge of any reasonable basis for any such claim.
- **15.1.6 Knowledge Of Pending Or Threatened IP Litigation**. It is not aware of any pending or threatened claim or litigation that alleges that its activities up to the Effective Date arising from the practice of the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement have violated the intellectual property rights of any Third Party, and it has no knowledge of any reasonable basis for any such claim.
- **15.1.7 Other Transactions**. Adaptimmune has not previously entered and will not enter into any agreement or arrangement during the Term of this Agreement, whether written

or oral, pursuant to which it has assigned, transferred, licensed, conveyed, or encumbered, or will or is obligated to assign, transfer, license, convey, or encumber, its rights, title, or interests in or to the Adaptimmune Background IP that is, or is to be, licensed to Universal Cells under this Agreement such that the relevant Patent Rights and Know-How may cease to be Controlled by Adaptimmune.

- **15.2 Universal Cells.** Universal Cells represents, warrants, and covenants to Adaptimmune as of the Effective Date that:
- **15.2.1 Ownership Of Intellectual Property**. Except as set forth in <u>Schedule 15.2.1</u>, Universal Cells is the sole legal and beneficial owner of the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement and to its knowledge Universal Cells has obtained written assignments of all rights, title, and interests from inventors of such Universal Cells Background IP.
- **15.2.2 Inventorship**. It is not aware of any Third Party who has made an inventive contribution to any of the inventions disclosed and claimed in the Patent Rights within the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement, other than those inventors named as inventors in such Patent Rights.
- **15.2.3 Prosecution and Maintenance**. It has complied with all Applicable Laws in all material respects, including any disclosure requirements, in connection with the filing, prosecution, and maintenance of the Patent Rights within the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement.
- **15.2.4 Misappropriation**. To its knowledge, the conception, development, and reduction to practice of the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement has not constituted nor involved the misappropriation of trade secrets or other rights or property of any Third Party.
- **15.2.5 Knowledge Of Pending Or Threatened IP Challenge.** Other than the intellectual property Controlled by Universal Cells listed in <u>Schedule 15.2.5</u>, it is not aware of any claim made against it asserting the invalidity, misuse, unregisterability, unenforceability, or non-infringement of any Patent Rights within the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement, or challenging its right to use or ownership thereof, or making any adverse claim of ownership thereof, and it has no knowledge of any reasonable basis for any such claim.
- **15.2.6 Knowledge Of Pending Or Threatened IP Litigation**. It is not aware of any pending or threatened claim or litigation that alleges that its activities up to the Effective Date arising from the practice of the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement have violated the intellectual property rights of any Third Party, and it has no knowledge of any reasonable basis for any such claim.
- **15.2.7 Other Transactions**. Universal Cells has not previously entered and will not enter into any agreement or arrangement during the Term of this Agreement, whether written or oral, pursuant to which it has assigned, transferred, licensed, conveyed, or encumbered, or will or is obligated to assign, transfer, license, convey, or encumber, its rights, title, or interests

in or to the Universal Cells Background IP that is, or is to be, licensed to Adaptimmune under this Agreement such that the relevant Patent Rights and Know-How may cease to be Controlled by Universal Cells.

- **15.3 Both Parties.** Each Party represents, warrants, and covenants warrants to the other Party as of the Effective Date that:
- **15.3.1 Representation Of Authority; Consents.** As of the Effective Date, (a) it has full right, power, and authority to enter into this Agreement, (b) this Agreement has been duly executed by such Party and constitutes a legal, valid, and binding obligation of such Party, enforceable in accordance with its terms, (c) it has the full legal power to grant the rights and licenses granted to the other Party under this Agreement, and (d) all necessary consents, approvals, and authorizations of all government authorities and other persons required to be obtained by such Party in connection with the execution, delivery, and performance of this Agreement have been and shall be obtained.
- **15.3.2 No Conflict.** Notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate such Party's corporate charter and bylaws or any requirement of Applicable Laws or regulations and (b) do not conflict with, violate, breach, or constitute a default or require any consent under, any contractual obligation of such Party.
- 15.3.3 Employee and Consultant Obligations. All of its employees, officers, and consultants and those of its Affiliates, in each case, that are supporting the performance of its obligations under this Agreement shall have executed agreements or have existing obligations under law requiring, in the case of employees and officers, assignment to such Party of all inventions made during the course of and as the result of their association with such Party and, in the case of employees, officers, and consultants, obligating the individual to maintain as confidential such Party's Confidential Information as well as confidential information of a Third Party that such Party may receive, to the extent required to support such Party's obligations under this Agreement.

## 15.3.4 Third Party Agreements.

- (a) Each Party has disclosed to the other Party true and correct copies of all in-license agreements to which it is a party and pursuant to which it is sublicensing any Patent Rights or Know-How to the other Party under this Agreement.
- (b) It is not in breach of any agreement with any Third Party that would affect its obligations or the other Party's rights under this Agreement and that it is not in default under any of its existing licenses with any Third Party reasonably necessary for it to fulfill its duties and obligations under this Agreement.
- (c) Each Party shall maintain such Third Party licenses in effect during the term of the Agreement and if it has been accused of a material breach under any such Third Party agreements or licenses, then it shall within ten (10) days of such accusation notify the other Party of such accusation.

- **15.3.5 Knowledge Of Pending Or Threatened Litigation.** There is no claim, investigation, suit, action, or proceeding pending or, to the knowledge of such Party, expressly threatened, against such Party before or by any Governmental Authority that, individually or in the aggregate, could reasonably be expected to materially impair the ability of such Party to perform any obligation under this Agreement.
- 15.4 Disclaimer Of Warranty. Nothing in this Agreement shall be construed as a representation made or warranty given by either Party that any patents will issue based on pending applications or that any such pending applications or patents issued thereon will be valid. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

### **ARTICLE 16**

## INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY

- 16.1 Indemnification By Adaptimmune. Adaptimmune agrees to defend Universal Cells, its Affiliates, and each of their respective directors, officers, employees and agents (the "Universal Cells Indemnified Parties"), at Adaptimmune's cost and expense, and will indemnify and hold Universal Cells and the other Universal Cells Indemnified Parties harmless from and against any claims, losses, costs, damages, fees, or expenses (including reasonable legal fees and expenses) (collectively, "Losses") to the extent resulting from any claims, actions, suits, or proceedings brought by a Third Party (including product liability claims) (a "Third Party Claim") arising out of (a) the gross negligence or willful misconduct of Adaptimmune, its Affiliates or their respective sublicensees in connection with the performance of its activities under this Agreement; (b) [\*\*\*]; or (c) the Development, Manufacture, Commercialization, or other exploitation of any or Unilateral Adaptimmune Product by or on behalf of Adaptimmune, its Affiliates, or their respective sublicensees (including from product liability and intellectual property infringement claims); except, in each case, to the extent such Losses result from clause (a), (b), or (c) of Section 16.2 (Indemnification By Universal Cells).
- 16.2 Indemnification By Universal Cells. Universal Cells agrees to defend Adaptimmune, its Affiliates and their respective directors, officers, employees and agents (the "Adaptimmune Indemnified Parties"), at Universal Cells' cost and expense, and will indemnify and hold Adaptimmune and the other Adaptimmune Indemnified Parties harmless from and against any Losses to the extent resulting from any Third Party Claims arising out of (a) the gross negligence or willful misconduct of Universal Cells, its Affiliates, or their respective sublicensees in connection with the performance of its activities under this Agreement; (b) [\*\*\*]; or (c) the Development, Manufacture, Commercialization, or other exploitation of any Universal Cells Program Product or Unilateral Universal Cells Product by or on behalf of Universal Cells, its Affiliates, or their respective sublicensees (including from product liability and intellectual property infringement claims); except, in each case, to the extent such Losses result from clause (a), (b), or (c) of Section 16.1 (Indemnification By Adaptimmune).

- **16.3 Indemnification Procedure**. The foregoing indemnity obligations shall be conditioned upon (a) the indemnified Party ("**Indemnitee**") promptly notifying the indemnifying Party ("**Indemnitor**") in writing of the assertion or the commencement of the relevant Third Party Claim (*provided*, *however*, that any failure or delay to notify shall not excuse any obligation of the Indemnitor, except to the extent the Indemnitor is actually prejudiced thereby), (b) the Indemnitee granting the Indemnitor sole management and control, at the Indemnitor's sole expense, of the defense of such Third Party Claim and its settlement; *provided*, *however*, that the Indemnitor shall not settle any such Third Party Claim without the prior written consent of the Indemnitee if such settlement does not include a complete release from liability or if such settlement would involve the Indemnitee undertaking an obligation (including the payment of money by the Indemnitee), would bind or impair the Indemnitee, or includes any admission of wrongdoing by the Indemnitee or any admission that any Patent Right or other intellectual property right of Indemnitee or this Agreement is invalid, narrowed in scope, or unenforceable, and (c) the Indemnitee reasonably cooperating with the Indemnitor (at the Indemnitee's expense). The Indemnitee shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification.
- **16.4 Insurance**. Each of the Parties will, at their own respective expense procure and maintain during the Term, insurance policies adequate to cover their obligations hereunder and consistent with the normal business practices of prudent biopharmaceutical companies of similar size and scope (or reasonable self-insurance sufficient to provide materially the same level and type of protection). Such insurance will not create a limit to either Party's liability hereunder.
- 16.5 Limitation of Liability. IN NO EVENT SHALL A PARTY BE LIABLE HEREUNDER TO THE OTHER PARTY FOR ANY PUNITIVE, INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES (INCLUDING LOST REVENUE, LOST PROFITS, OR LOST SAVINGS) HOWEVER CAUSED AND UNDER ANY THEORY, EVEN IF IT HAS NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE LIMITATIONS SET FORTH IN THIS SECTION 16.5 SHALL NOT APPLY WITH RESPECT TO ANY BREACH OF ARTICLE 10 (EXCLUSIVITY) OR ARTICLE 12 (CONFIDENTIALITY). NOTHING IN THIS SECTION 16.5 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTION 16.1 (INDEMNIFICATION BY ADAPTIMMUNE) OR SECTION 16.2 (INDEMNIFICATION BY UNIVERSAL CELLS) WITH RESPECT TO ANY DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A THIRD PARTY CLAIM.

#### **ARTICLE 17**

## MISCELLANEOUS PROVISIONS

**17.1 Governing Law**. This Agreement shall be governed and the respective rights of the Parties determined according to the substantive laws of the State of New York without giving effect to any choice of law principles that would require the application of the laws of a different state.

#### 17.2 **Successors and Assigns.**

**17.2.1 Assignment**. This Agreement may not be assigned by either Party without the prior written consent of the other Party, except that either Party shall be free to assign this Agreement in whole or in part (a) to an Affiliate of such Party (for so long as such Affiliate remains an Affiliate) provided that such Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate, or (b) in connection with any sale to a Third Party of all or substantially all of the assets of the Party that relate to this Agreement, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets, or otherwise (a "Sale Transaction"). This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the Parties hereto. Any attempted assignment of this Agreement in contravention of this Section 17.2.1 (Assignment) shall be null and void.

## 17.2.2 After-Acquired Intellectual Property

[\*\*\*].

17.2.3 [\*\*\*].

17.3 Entire Agreement; Amendments. The Existing Agreement, this Agreement, and the Schedules referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral. Neither Party shall be bound by or charged with any written or oral agreements, representations, warranties, statements, promises or understandings not specifically set forth in this Agreement. No amendment, supplement or other modification to any provision of this Agreement shall be binding unless in writing and signed by Universal Cells and Adaptimmune.

#### 17.4 **Notices**. Notices to Adaptimmune shall be addressed to:

Chief Business Officer at the registered office address for Adaptimmune Limited

with a copy to: General Counsel at the registered office address for Adaptimmune Limited

Notices to Universal Cells shall be addressed to:

Attn: [\*\*\*] Universal Cells 3005 1st Avenue Seattle, WA 98121 Email: [\*\*\*]

with a copy to:

Attention: General Counsel

Astellas US LLC

1 Astellas Way Northbrook, IL 60062 Email: [\*\*\*]

Either Party may change its address to which notices shall be sent by giving notice to the other Party in the manner herein provided. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be (a) sent by registered or certified mail, return receipt requested, postage prepaid, (b) sent via a reputable overnight courier service, or (c) sent by email with return receipt requested, in each case, properly addressed in accordance with this Section 17.4. The effective date of notice shall be the actual date of receipt by the Party receiving the same.

- **17.5 Force Majeure**. No failure or omission by either Party in the performance of any obligation of this Agreement (other than any failure to make payments as and when due under this Agreement) shall be deemed a breach of this Agreement or create any liability if the same shall arise from acts of gods; acts of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; or terrorism or invasion; *provided* that the Party affected by such cause promptly notifies the other Party and uses reasonable efforts to cure such failure or omission as soon as is practicable after the occurrence of one or more of the above mentioned causes.
- 17.6 Compliance With Law; Severability. Nothing in this Agreement shall be construed to require the commission of any act or omission contrary to Applicable Law. If any one or more provisions of this Agreement is held to be invalid, illegal, or unenforceable, then the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements and the validity, legality, and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.
  - 17.7 Non-Solicitation. [\*\*\*].
- 17.8 Independent Contractors. The relationship between Universal Cells and Adaptimmune created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture, or similar business relationship between the Parties, including for all tax purposes. No such Party is a legal representative of the other Party, and no such Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Each such Party shall use its own discretion and shall have complete and authoritative control over its employees and the details of performing its obligations under this Agreement.
- **17.9 No Strict Construction**. This Agreement has been prepared jointly and shall not be strictly construed against either Party.
- **17.10 Headings**. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.

- **17.11 No Implied Waivers; Rights Cumulative.** No failure on the part of Adaptimmune or Universal Cells to exercise, and no delay in exercising, any right, power, remedy, or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy, or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy, or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy, or privilege.
- **Interpretation.** Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural shall include the singular, and the use of any gender shall be applicable to all genders. The term "including" as used herein means including, without limiting the generality of any description preceding such term. The word "will" shall be construed to have the same meaning and effect as the word "shall." The word "or" will not be exclusive. References to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement. The words "herein," "hereof," and "hereunder" and words of similar import will be construed to refer to this Agreement in its entirety and not to any particular provision hereof. All references to a "business day" or "business days" in this Agreement means any day other than a day that is a Saturday, a Sunday or any day banks are authorized or required to be closed in the State of New York. The word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement. Provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (including email, but excluding instant messaging). When used in this Agreement "knowledge" will not require any freedom to operate or other similar searching to be performed by the applicable Party. The language in all parts of this Agreement shall be deemed to be the language mutually chosen by the Parties. The Parties and their counsel have cooperated in the drafting and preparation of this Agreement, and this Agreement therefore shall not be construed against any Party by virtue of its role as the drafter thereof.
- **17.13 Execution In Counterparts.** This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.
- **17.14 No Third Party Beneficiaries**. No person or entity other than Universal Cells and Adaptimmune and permitted assignees hereunder shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- 17.15 Subcontracting; Performance by Affiliates. Each Party may engage its Affiliates or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform certain of its obligations under this Agreement without the prior written consent of the other Party. Any Affiliate or Third Party subcontractor to be engaged by a Party to perform such Party's obligations set forth in this Agreement will meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity. The activities of any such Third Party subcontractors or Affiliates performing on behalf of a Party under this Agreement will be considered activities of such subcontracting Party under this Agreement. The subcontracting Party will be responsible for

ensuring compliance by any such Third Party subcontractors or Affiliates with the terms of this Agreement, as if such Third Party(ies) or Affiliate are such Party hereunder. Notwithstanding the foregoing, the second, third, and fourth sentence of this Section 17.15 does not apply to activities related primarily to Universal Cells Program Targets and Universal Cells Program Products.

17.15.1 If [\*\*\*] engages an Affiliate to perform activities pursuant to this Agreement, then [\*\*\*] shall enter into an arrangement with such Affiliate immediately prior to the commencement of such activities under which any Patent Rights and Know-How arising in the course of such Affiliate's performance of such activities shall be either assigned to [\*\*\*], or licensed to [\*\*\*] as necessary to render such Patent Rights and Know-How to be Controlled by [\*\*\*] for purposes of this Agreement. Furthermore, [\*\*\*] agrees not to undertake any transfer of Patent Right or Know-How that is licensed to [\*\*\*] pursuant to this Agreement to any Affiliate after the Effective Date in a manner that would render any such Patent Rights or Know-How to no longer be Controlled by [\*\*\*] pursuant to this Agreement.

[Signature Page Follows]

**IN WITNESS WHEREOF**, the Parties have caused their duly authorized representative to execute this Agreement as of the date first set forth above.

## ADAPTIMMUNE LIMITED

By: /s/ Helen Tayton-Martin

Name: Helen Tayton-Martin

Title: Chief Business Officer

## UNIVERSAL CELLS, INC.

By: /s/ Noburu Yamaji

Name: Noburu Yamaji

Title: President

The following Schedules are being simultaneously delivered with the execution of this Agreement as separate documents:

# Schedule 1.90 Tables, Figures, and Listings

**Tables, Figures and Listings for Phase 1 Trial** 

[\*\*\*]

Schedule 2.2.1 JSC Members

Adaptimmune members: [\*\*\*]

Universal members: [\*\*\*]

# Schedule 2.3.1 JRC Members

Adaptimmune members: [\*\*\*]

Universal members: [\*\*\*]

## Schedule 2.4.2 Astellas Publication Policy

THIS PAGE AND THE FOLLOWING 9 PAGES OF THIS SCHEDULE HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

[\*\*\*]

#### Schedule 11.3

#### **Collaboration Product Profit Share**

#### 1. **DEFINED TERMS**

- 1.1 "Clinical Supply Costs" means with respect to a Collaboration Profit-Share Product, standard costs for such Collaboration Profit-Share Product as of the time of clinical Manufacture as calculated in a manner consistent with a Party's other products and to the extent within [\*\*\*] of the budgeted amount set forth in the applicable Co-Development Budget. [\*\*\*].
- 1.2 "Commercialization Costs" means all Costs incurred by a Party and its Affiliates during the Term and pursuant to this Agreement for the Commercialization of Collaboration Profit-Share Products as set forth under the Co-Commercialization Plan to the extent within [\*\*\*] of the budgeted amount set forth in the applicable Co-Commercialization Budget, [\*\*\*].
- 1.3 "Costs" means both internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate and all Out of Pocket Costs).
- 1.4 "**Development Costs**" means the direct costs incurred by a Party and its Affiliates during the Term and pursuant to this Agreement for the Development of Collaboration Profit-Share Products as set forth under the Co-Development Plan to the extent within [\*\*\*] of the budgeted amount set forth in the applicable Co-Development Budget, calculated as the sum of (a) Out-of-Pocket Development Expenses; (b) Development FTE Costs; (c) Clinical Supply Costs; and (d) Other Development Costs. [\*\*\*].
- 1.5 **"Development FTE Costs"** means the product of (a) the actual number of FTEs utilized in the Development of Collaboration Profit-Share Products in accordance with the applicable Co-Development Plan and to the extent set forth in the applicable Co-Development Budget, as documented by a Party and (b) the FTE Rate.
- 1.6 "**Manufacturing Costs**" means the following Costs incurred by a Party and its Affiliates during the Term to produce Collaboration Profit-Share Products for Commercialization in the Territory: [\*\*\*].
- 1.7 **"Medical Affairs Activities Costs"** means Costs incurred by a Party and its Affiliates during the Term and pursuant to this Agreement associated with Medical Affairs Activities conducted for the Collaboration Profit-Share Products in the Territory, [\*\*\*].
- 1.8 **"Other Development Costs"** means any other costs or expenses incurred for clinical materials, analytical services, or other items with respect to a Collaboration Profit-Share Product to the extent set forth in the applicable Co-Development Budget.
- 1.9 **"Out-of-Pocket Development Costs"** means direct expenses paid or payable to Third Parties that are specifically identifiable and incurred by a Party and its Affiliates for the

Development of Collaboration Profit-Share Product(s) and set forth in the applicable Co-Development Budget; [\*\*\*].

- 1.10 **"Profit"** means, with respect to activities conducted by a Party and its Affiliates with respect to the Collaboration Profit-Share Products during any Calendar Quarter, the positive or negative difference between [\*\*\*]. For the sake of clarity, Profit shall be determined prior to application of any net income and franchise or similar types of taxes.
- 1.11 "Program Costs" means, with respect to a Collaboration Profit-Share Product for any Calendar Quarter, the following expenses that are incurred by a Party and any of its Affiliates: (a) Manufacturing Costs; (b) Commercialization Costs; (c) Medical Affairs Activities Costs; (d) payments to Third Parties for access to intellectual property rights; (e) costs associated with recalls, corrective actions, market withdrawals, or similar actions; (f) Losses arising from Third Party Claims that are specifically identifiable or reasonably allocable to the Commercialization of a Collaboration Profit-Share Product; and (g) costs associated with a Party's obligations with respect to regulatory matters under Article 5 (Co-Development of Collaboration Profit-Share Products) and Article 6 (Co-Commercialization of Collaboration Profit-Share Products), in each case, to the extent within [\*\*\*] of the amounts set forth in the applicable Co-Development Budget and intellectual property matters under Article 9 (Licenses; Options; Intellectual Property). Development Costs are not included in Program Costs and *vice-versa*. If any cost or expense is directly attributable or reasonably allocable to more than one activity, such cost or expense shall only be counted as Program Costs with respect to one of those activities.
- 1.12 **"Sublicensing Revenues"** means all revenues or other consideration received by a Party or its Affiliates from a sublicensee (excluding royalties) as consideration for the grant of a sublicense under the licenses granted to a Party with respect to Collaboration Profit-Share Products, to the extent allocable to rights sublicensed with respect to the Territory.
- 2. PROFIT SHARE ALLOCATION IN ACCORDANCE WITH SECTION 11.3.
- 2.1 **Allocation of the Profit**. Each Party shall account for Program Costs and Development Costs in accordance with its accounting standards. Universal Cells shall be entitled to receive fifty percent (50%) of the Profit and Adaptimmune shall be entitled to receive fifty percent (50%) of the Profit.
- 2.2 **Allocation of Development Costs.** Universal Cells shall pay fifty percent (50%) of Development Costs and Adaptimmune shall pay fifty percent (50%) of Development Costs.
- 2.3 **Reports and Payments.** From and after the date upon which a Collaboration Target becomes a Collaboration Profit-Share Target, within [\*\*\*] after the end of each Calendar Quarter, each Party shall provide the other Party and the JFC with a report specifying in reasonable detail Net Sales of Collaboration Profit-Share Products by such Party, its Affiliates, and its sublicensees in the Territory, as well as Sublicensing Revenues received, recoveries pursuant to Section 9.9 (Patent Enforcement), and Development Costs and Program Costs incurred by such Party or its Affiliates, in such Calendar Quarter. The JFC will review such reports within [\*\*\*] days or receiving the second of such reports for a

Calendar Quarter issue to the Parties a reconciliation report that will include a reconciliation of the Development Costs and Program Costs incurred by the Parties, the calculation of Profit in accordance with this <u>Schedule 11.3</u>, and the amount payable by the applicable Party to the other Party in order to achieve the cost-sharing and profit-sharing contemplated such Sections 2.1 (Allocation of the Profit) and 2.2 (Allocation of Development Costs) of this <u>Schedule 11.3</u>. Based on such report, the Party to whom a payment is owed in order to achieve such allocations and profit-sharing shall issue an invoice to the other Party for the appropriate amount, and the owing Party shall make the applicable payment within [\*\*\*] after receiving such invoice.

2.4 **Tax Matters**. For the avoidance of doubt, each Party shall be responsible for all income taxes imposed on such Party's share of the Profit.

#### Schedule 12.4

#### **Press Release**

# Astellas and Adaptimmune Enter into Agreement to Co-Develop and Co-Commercialize Stem-Cell Derived Allogeneic CAR-T and TCR T-Cell Therapies

TOKYO and PHILADELPHIA, PA, OXFORDSHIRE, United Kingdom, January XX, 2020 (GLOBE NEWSWIRE) -- Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas"), through its wholly-owned subsidiary Universal Cells, Inc, and Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in cell therapy to treat cancer, announced that they have entered into a co-development and co-commercialization agreement to bring new stem-cell derived allogeneic T-cell therapies to people with cancer.

Astellas and Adaptimmune will agree on up to three targets and co-develop T-cell therapy candidates directed to those targets. These targets will exclude target specific T-cell products in pre-clinical or clinical trials or those developed for other partners at Adaptimmune. The collaboration will leverage Adaptimmune's target identification and validation capabilities for generating target-specific T-cell Receptors (TCRs), chimeric antigen receptors (CARs), and HLA-independent TCRs that recognize surface epitopes independently of the HLA profile of the tumor cell. The collaboration will also utilize Astellas' Universal Donor Cell and Gene Editing Platform it obtained through the acquisition of Seattle-based Universal Cells.

Adaptimmune has been collaborating with Universal Cells (now an Astellas Company) since 2015 on development of gene-edited iPSC cell lines, for which Adaptimmune has rights to develop and commercialize resulting T-cell therapy products using its proprietary process for generating T cells from stem cells without the use of feeder cell lines.

Astellas will fund research up until completion of a Phase 1 trial for each candidate. Upon completion of the Phase 1 trial for each candidate, Astellas and Adaptimmune will elect whether to progress with co-development and co-commercialization of the candidate, or to allow the other Party to pursue the candidate independently through a milestone and royalty bearing licence, with the agreement allowing for either company to opt out. The companies will each have a co-exclusive licence covering the co-development and co-commercialization of the product candidates within the field of T-cell therapy. If a candidate is developed by one company only, the appropriate licences will become exclusive to the continuing party.

"Astellas positions immuno-oncology as one of its strategic areas of primary focus, and it is engaged in the development of novel therapies for cancer patients using a new modality/technology," stated Naoki Okamura, Representative Director Corporate Executive Vice President, Chief Strategy Officer and Chief Financial Officer, Astellas. "In addition to NK cells, T-cells are an important component of cell therapy for immuno-oncology, and we look forward that this agreement with Adaptimmune will enable us to create new stem-cell derived allogeneic T-cell therapies for a variety of cancers, including solid tumors, in the future. We will continue to dedicate our efforts in delivering novel treatments for diseases with high unmet medical needs, pursuing cutting-edge science and technological advances."

"We are delighted to establish this significant co-development partnership with Astellas, which builds upon and substantially extends an existing collaboration focused on gene editing of iPSC cells," said Helen Tayton-Martin, Adaptimmune's Chief Business Officer and Co-Founder. "This new collaboration may encompass both CAR-T and TCR T-cell approaches, including our novel HLA-independent TCR ("HiT") platform. It brings together highly complementary skills and expertise across the two organizations, and will enable the accelerated development of new, off-the-shelf T-cell therapy products for people with cancer."

Astellas will also have the right to select two targets and develop allogeneic cell therapy candidates independently. Astellas will have sole rights to develop and commercialize these products, subject to necessary licenses and the payment of milestones and royalties.

Under the terms of the agreement, Adaptimmune may receive up to \$897.5 million in payments, including:					
an upfront payment of \$50 million.					
development milestones totalling up to \$73.75 million for each product if the collaboration product discovered in this partnership is co-developed and commercialized by both companies					
Up to \$147.5 million in milestone payments per product and up to \$110 million in sales milestones for products developed unilaterally by Astellas.					
In addition, Adaptimmune will receive research funding of up to \$7.5 million per year.					
Finally, Adaptimmune would receive tiered royalties on net sales in the mid-single to mid-teen digits.					
Under the terms of the agreement, Astellas may receive up to \$552.5 million, including:  Up to \$147.5 million in milestone payments per product and up to \$110 million in sales milestones.					
In addition, Astellas would receive tiered royalties on net sales in the mid-single to mid-teen digits.					

To the extent that Astellas and Adaptimmune co-develop and co-commercialize any T-cell therapy, they will equally share the costs of such co-development and co-commercialization, with the resulting profits from co-commercialization also shared equally. Further details governing co-development and co-commercialization will be articulated in a product-specific commercialization agreement.

The impact of this transaction on Astellas' financial results in the fiscal year ending March 31, 2020 will be limited.

### **About Adaptimmune**

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products for people with cancer. The Company's unique SPEAR

(Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer across multiple solid tumors. For more information, please visit http://www.adaptimmune.com.

#### **About Astellas**

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at https://www.astellas.com/en

#### **Adaptimmune Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 6, 2019, and our other SEC filings. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

#### **Cautionary Notes Regarding Forward-Looking Statements (Astellas)**

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

# **Schedule 15.1.1**

THIS PAGE AND THE FOLLOWING 8 PAGES OF THIS SCHEDULE HAVE BEEN OMITTED AND FILED
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF
THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

[\*\*\*].

## Schedule 15.2.1

THIS PAGE AND THE FOLLOWING 4 PAGES OF THIS SCHEDULE HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

[\*\*\*]

# **Schedule 15.2.5**

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

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PRIVATE & CONFIDENTIAL

**AGREEMENT** 

**BETWEEN:** 

**ADAPTIMMUNE LIMITED (1)** 

and

**UNIVERSAL CELLS, INC. (2)** 

AMENDED AND RESTATED RESEARCH COLLABORATION
AND LICENCE AGREEMENT RELATING TO GENE EDITING
AND HLA-ENGINEERING TECHNOLOGY

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Schedule 8 - Partner Notice

This AMENDED AND RESTATED **RESEARCH COLLABORATION AND LICENCE AGREEMENT** (the "**Agreement**") is made as of the 25th day of November 2015 (the "**Effective Date**") and amended as of January 13, 2020 (the "**Amendment Date**") by and between:

(1) **ADAPTIMMUNE LIMITED,** a company incorporated in England and Wales with its registered address at 101 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY ("Adaptimmune");

#### and

(2) **UNIVERSAL CELLS, INC.**, a company incorporated in the State of Washington with its principal address at 3005 1<sup>st</sup> Ave, Seattle, WA 98121 ("Universal").

#### **Background**

- (A) WHEREAS Universal has taken a licence from the University of Washington in relation to certain Intellectual Property Rights for Gene Editing Technology, HLA Engineering Technology and a cell line (defined further below) and has certain related know-how;
- (B) WHEREAS Adaptimmune is a clinical-stage biopharmaceutical company focused on immunotherapy products based on its T-cell receptor platform;
- (C) WHEREAS Universal has experience and related know-how for the development of a 'universal' cell line;
- (D) WHEREAS the parties wish to conduct certain collaborative development activities;
- (E) WHEREAS Adaptimmune wishes to acquire exclusive rights to certain work product and intellectual property rights arising from collaborative development activities together with certain pre-existing intellectual property rights; and
- (F) WHEREAS the parties have agreed to collaborate on the terms and conditions set out below.

#### Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Universal and Adaptimmune intending to be legally bound, agree as follows:

#### 1. Definitions

Unless otherwise specifically provided herein, the following terms, when used with a capital letter at the beginning, shall have the following meanings:

1.1. "AAV/HLA-engineering Licence" means the Licence and Material Transfer Agreement between Universal and the University of Washington dated 27 June 2014 and attached as Schedule 5;

- 1.2. "Adaptimmune Technology" means the gene sequence provided by Adaptimmune encoding the affinity engineered TCR intended for expression in any transduced T-cell and the resulting amino-acid sequence transcribed from such gene sequence.
- 1.3. "Affiliate" means, with respect to a Person, any Person that directly, or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with such first Person.
- 1.4. "Anti-Corruption Laws" means the US Foreign Corrupt Practices Act 1977, the UK Bribery Act 2010 and any other Applicable Laws for the prevention of fraud, corruption, racketeering, money laundering or terrorism.
- 1.5. **"Applicable Law"** means the applicable laws, rules and regulations in the world, including any rules, regulations, guidelines or other requirements of the Governmental Authorities that may be in effect from time to time and in each case to the extent they apply to a party's performance of its obligations under this Agreement. Applicable Law shall include compliance with GMP.
- 1.6. **"Arising IP"** means any Intellectual Property Rights first conceived, first generated or reduced to practice (excluding any inventions first conceived outside of the performance of the Research Program) in the performance of the Research Program by or on behalf of either Party including performance by any contractors or sub-contractors or Affiliates of either Party.
- 1.7. **"BioInformation Pipeline"** means that set of technology and tools developed by or on behalf of, and Controlled by, Universal outside of the Research Program for use in the analysis and interpretation of whole exome sequencing to identify clinically relevant variants.
- 1.8. **"BioInformatic Results"** means data and information Controlled by Universal and arising from use of the BioInformatic Pipeline.
- 1.9. **"Breaching Party"** has the meaning set forth in Section 15.3.
- 1.10. "Business Day" means a day other than Saturday or Sunday or a public holiday in the United States of America and England.
- 1.11. "Change in Control" means a transaction pursuant to which Third Parties (a) that did not have Control prior to the applicable transaction acquire (whether by merger, consolidation or transfer or issuance of capital stock or otherwise) the Control of such Person, or (b) acquire assets constituting all or substantially all of the assets of such Person or in the case of Universal, assets constituting all or substantially all of either the Universal Technology or rights under the Universal Patents; other than (i) the initial public offering of the common stock of a Person in a public market; or (ii) any sale or transfer of the capital stock owned or controlled by the majority stockholder or stockholders of a Person to trusts or comparable entities for the primary benefit of such stockholders or their family members or to the estate, heirs or devisees of any such stockholder in the event of his or her death; or (iii) any transaction in which a Person reincorporates in another jurisdiction or engages in other internal reorganization or

changes in corporate structure but where there is no change in Control of such Person or change in ownership of any assets.

- 1.12. "Commercially Reasonable Efforts" means with respect to the research, development, manufacture or commercialisation of a Product, at least the same efforts and resources used by a biopharmaceutical company for similar products with similar commercial and scientific potential at a similar stage in their development or lifecycle or in a similar therapeutic area taking into consideration their safety and efficacy, their cost to develop, the competitiveness of alternative products and the nature and extent of their market exclusivity (including Patent coverage and regulatory exclusivity), the likelihood of Regulatory Approval, and their expected profitability and level of pricing and reimbursement, including the amounts of marketing and promotional expenditures with respect to the Products and generic products. Commercially Reasonable Efforts shall be determined based on the world as a whole and without reference to specific markets or group of markets.
- 1.13. "Competitor" means any Person which Exploits products or therapies for immunotherapy and wherein such product or therapy incorporates a genetically engineered T-cell including where such Person is listed as a competitor or having a competitive offering in Adaptimmune's publicly available filings with the Securities Exchange Commission including its 20-F as filed at the Effective Date.
- 1.14. **"Complaining Party"** has the meaning set forth in Section 15.3.
- 1.15. **"Confidential Information**" means, subject to Section 11, any and all confidential data, results, know-how, plans, business information and other Information, whether oral or in writing or in any other form, disclosed before, on or after the date of this Agreement by one Party or its Affiliates to another Party or its Affiliates or sub-contractors, including the terms and existence of this Agreement.
- 1.16. "Control" means, with respect to any item of Information, Patent or Intellectual Property Right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Information, Patent or Intellectual Property Right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party and without owing any payment to a Third Party in relation to such assignment, grant, license, sublicense or other right. "Control" with respect to any Person and for the purposes of Sections 1.3 and 1.11 means (a) the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise; or (b) to own directly or indirectly 50% or more of the outstanding voting securities or other ownership interest of such Person. The terms "Controlled by" and "under common Control with" shall be interpreted accordingly.
- 1.17. **"Cover"** means, with respect to a particular Patent or patent application and with reference to a specific product, service or process, that the use, manufacture, sale, offer to sale, supply or import of such product, service or process would infringe a claim of such Patent or patent application.

- 1.18. **"Deliverable"** means any tangible deliverable provided to Adaptimmune by Universal during the course of the Research Program and specified as a Deliverable in such Research Program including for clarity any cell bank or cell line provided by Universal.
- 1.19. **"Development Milestone"** shall have the meaning provided in Section 6.2.
- 1.20. **"Disclosing Party"** has the meaning set forth in Section 11.1.
- 1.21. "**Effective Date**" has the meaning set forth in the preamble to this Agreement.
- 1.22. **"Elf Licence"** means the Non-exclusive License Agreement between Universal and the University of Washington dated 22 October 2014 and attached as Schedule 6.
- 1.23. **"EMA"** means the European Medicines Agency and its successors.
- 1.24. "Exploit" means to keep, make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, manufacture, have manufactured, hold/keep (whether for disposal or otherwise), formulate, optimise, have used, export, transport, distribute, promote, market or have sold or otherwise dispose or offer to dispose of, a product or process. Exploiting shall be interpreted accordingly.
- 1.25. **"Exploitation"** means the act of Exploiting a product or process.
- 1.26. "FDA" means the United States Food and Drug Administration and any successor agency thereto.
- 1.27. **"Field"** means immunotherapy and wherein the administered product or therapy incorporates a form of T-cells including, but without limitation, genetically engineered T-cells or stem cell derived T-cells.
- 1.28. "First Commercial Sale" means the first sale for monetary value of a Product in any country after Regulatory Approval in such country. For the avoidance of doubt, sales prior to receipt of the required Regulatory Approval, on a country-by-country basis required to commence regular commercial sales, such as so-called "treatment IND sales", "named patient sales" and "compassionate use sales", shall not be construed as a First Commercial Sale.
- 1.29. **"First Multi-Indication Product"** means the first Product for which Adaptimmune applies for an IND in more than one Indication.
- 1.30. "Gene Editing Technology" means the recombinant adeno-associated virus (rAAV)-mediated genome editing technology for the introduction, removal and disruption of chromosomal genes (including associated processes) developed by or on behalf of Universal prior to the Effective Date of this Agreement or thereafter outside of the performance of this Agreement.
- 1.31. "GMP" means the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

- 1.32. **"Governmental Authority"** means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Products.
- 1.33. "Government Official" means any individual person employed by or acting on behalf of a government, government-controlled entity (including any government hospitals or academic institutions) or public international organization; any political party, party official or candidate; any individual person who holds or performs the duties of an appointment, office or position created by custom or convention; and any individual person who holds himself or herself out to be the authorized intermediary of any of the foregoing.
- 1.34. "HLA Engineering Technology" means the use of the Gene Editing Technology to disrupt or prevent expression of [\*\*\*] or HLA class I and HLA class II via disruption of the B2M gene and RFXANK gene, and, in each case, to cause the expression of a single chain HLA-E protein via insertion of a gene into the B2M gene (including associated processes), and in each case as developed by or on behalf of Universal prior to the Effective Date or thereafter outside of the performance of this Agreement by Universal.
- 1.35. **"HLA Engineering Technology -Edited Cell Line"** means the [\*\*\*] Cell Line edited by Universal during performance of the Research Plan using the Universal Technology to produce a cell line that expresses only [\*\*\*] and that is produced via the [\*\*\*] and/or HLA class I and HLA class II via disruption of the B2M gene and RFXANK gene, and in each case to cause the expression of a single chain HLA-E protein via insertion of a gene into the B2M gene.
- 1.36. **"IND"** means an investigational new drug application filed with the FDA for authorisation to commence human clinical trials in the U.S., and/or its equivalent in other countries or regulatory jurisdictions in the world.
- 1.37. **"Indication**" means a disease, treatment area or therapeutic indication in relation to which any Product has obtained Regulatory Approval.
- 1.38. **"Indemnified Party"** means a Party, its Affiliates or its or their respective directors, officers and employees, seeking to recover a Loss under Section 14.1 or 14.2.
- 1.39. "Indemnifying Party" means Universal or Adaptimmune from whom recovery of a Loss is sought under Sections 14.1 or 14.2.
- 1.40. "Indirect Taxes" means value added taxes and sales taxes.
- 1.41. **"Information"** means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results, laboratory notes and notebooks, and other material, including: high-throughput screening, gene expression, genomics, proteomics and other drug discovery and development technology; biological, chemical, pharmacological, toxicological,

pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology; manufacturing and quality control procedures and data, including test procedures; and synthesis, purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and any products, apparatuses, cultures, biological materials and other materials and compositions.

- 1.42. "**Infringement Suit**" has the meaning set forth in Section 10.3.
- 1.43. "Intellectual Property Rights" means trademarks, service marks, trade secrets, trade names, registered designs, design rights, copyrights (including rights in computer software), domain names, database rights and any rights or property similar to any of the foregoing (excluding Patents) in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.
- 1.44. "[\*\*\*] **License Agreement**" means the Non-Exclusive License Agreement by and between [\*\*\*] and Universal dated [\*\*\*], [\*\*\*] pursuant to which Universal obtain a non-exclusive license under certain patent rights owned or controlled by [\*\*\*] that cover methods of reprogramming, or the compositions for reprogramming, the [\*\*\*] Cell Line claimed in the [\*\*\*] Licensed Patents.
- 1.45. "[\*\*\*] Licensed Patents" means the patent rights licensed to Universal pursuant the [\*\*\*] License Agreement, which are those patents and/or patent applications listed in Schedule 9 to this Agreement, and any and all patents and patent applications corresponding to those patents and patent applications worldwide including divisionals, continuations, continuations-in-part, renewals, reissues, re-examinations and extensions and any other patent term extensions and exclusivity periods and the like of any of the foregoing, and all counterparts of any of the foregoing in any country, which are owned or licensable by [\*\*\*], provided however that claims in the continuation-in-part applications are entitled to the priority filing date of the parent applications and are restricted to the subject matter claimed in or covered by the subject parent application.
- 1.46. "[\*\*\*] **Partner Notice**" shall mean the notified obligations set out in Schedule 8.
- 1.47. "JSC" shall have the meaning provided in Section 3.1.
- 1.48. "Licensee Improvement Patents" means [\*\*\*].
- 1.49. "Losses" means any and all direct liabilities, damages, losses or expenses, including interest, penalties, and reasonable lawyers' fees and disbursements. In calculating Losses, the legal duty to mitigate on the part of the Party suffering the Loss shall be taken into account. "Loss" shall be construed accordingly.
- 1.50. "Major Territory" means the United States, Germany, China, Japan, France or the UK.
- 1.51. **"Manufacturing Price"** means the cost of manufacture and supply of any Product as accounted for by Adaptimmune in accordance with its internal accounting policies (consistently applied) and including the following:

- a) cost of raw materials and intermediate materials including vector constructs;
- b) third party manufacture (including associated manufacturing and quality services) and supply costs for manufacture, quality control, distribution, release testing, packaging and supply of vector and Product;
- c) cost of any Third Party materials used in the manufacture or supply of product;
- d) payments made to Third Parties under any licences or consents and specific to manufacture, sale or supply of the relevant product;
- e) any taxes or charges payable (including customs charges or other charges) in relation to the shipping, import, export and supply of product or any intermediate materials or product required for manufacture of end product.
- f) Cost of patient administration including associated clinical care and any pre-conditioning or pre-treatment regimen required by patients; and
- g) Cost of any patient follow-up or other treatment occasioned as a result of treatment using product.
- 1.52. "Materials" means samples or other materials provided by a Party to another Party under this Agreement.
- 1.53. "Material Anti-Corruption Law Violation" means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement which would if it were publically known have a material adverse effect on a Party or on the reputation of a Party because of its relationship with the other Party.
- 1.54. "Mean Average Cost of Supply" shall mean the mean average of the Manufacturing Price in the applicable twelve (12) month period.
- 1.55. **"Net Sales"** means the gross invoiced amount on sales of the Products by Adaptimmune and its Affiliates and their respective sublicensees to Third Parties after deduction of the following that are specific for Products:
  - a) normal and customary trade, quantity or prompt settlement discounts (including chargebacks and allowances) actually allowed and taken;
  - b) normal and customary amounts repaid or credited by reason of rejection, returns or recalls of goods, rebates or bona fide price reductions determined by Adaptimmune or its Affiliates and sublicensees in good faith;
  - normal and customary rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program in the United States or equivalent governmental program in any other country;

- d) any invoiced amounts which are not collected by Adaptimmune or its Affiliates or licensees and which are not recovered under an insurance policy and which are written off by Adaptimmune as part of its accounting processes;
- e) excise taxes, Indirect Taxes, customs duties, customs levies and import fees imposed on the sale, importation, use or distribution of the Products; and
- f) any other similar and customary deductions that are consistent with generally accepted accounting principles.

Net Sales shall be calculated using Adaptimmune's internal audited systems used to report such sales as adjusted for any of items (a) to (f) above not taken into account in such systems. All amounts shall be determined from the books and records of Adaptimmune and its Affiliates and sublicensees, maintained in accordance with IFRS (or equivalent system) and consistently applied.

Sales between Adaptimmune and its Affiliates will not be Net Sales unless the sale is to an end user (other than for the purposes of research, development and manufacture) and there is no onward sale or supply. The transfer of Products for sampling purposes without monetary consideration shall be disregarded for the purposes of calculating Net Sales. Any free of charge disposal or use of a Product for regulatory or marketing purposes such as compassionate use or indigent patient programs, will not be deemed a sale or disposition for calculating Net Sales.

- 1.56. "[\*\*\*] Agreement" means the [\*\*\*] Material Transfer Agreement [\*\*\*] agreement dated [\*\*\*] which is attached as Schedule 7 to this Agreement (the "[\*\*\*] Agreement").
- 1.57. "[\*\*\*] Cell Line" means the cell line described as [\*\*\*] obtained by Universal from the [\*\*\*] pursuant to the [\*\*\*] Agreement and provided to Adaptimmune by Universal.
- 1.58. "**Notice Period**" has the meaning set forth in Section 15.3.
- 1.59. **"Other Edited Cell Lines**" means any cell lines developed in the performance of the Research Plan but excluding the [\*\*\*] Cell Line, the Sub-clone Cell Line and the HLA Engineering Technology-Edited Cell Line.
- 1.60. "Party" means Universal or Adaptimmune and "Parties" means both of Universal and Adaptimmune.
- 1.61. "Patents" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and

the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

- 1.62. **"Payments"** shall mean the payments and royalties to be paid by Adaptimmune to Universal in accordance with Section 6 of this Agreement.
- 1.63. **"Person"** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organisation, including a government or political subdivision, department or agency of a government.
- 1.64. "Phase" means a phase of the Research Program as summarised in Schedule 1.
- 1.65. **"Product Milestone"** shall have the meaning given in Section 6.5.
- 1.66. **"Products"** means any pharmaceutical product, service or therapy that contains, incorporates or uses any Deliverable provided by Universal under the Research Program.
- 1.67. **"Receiving Party"** has the meaning set forth in Section 11.1.
- 1.68. "Regulatory Approval" means an approval for a Product from a Governmental Authority necessary for the sale of a Product.
- 1.69. "Regulatory Documentation" means all applications, registrations, licenses, authorisations and approvals, all correspondence submitted to or received from Governmental Authorities (including minutes and official contact reports relating to any communications with any Governmental Authority) and all supporting documents and all clinical studies and tests, in each case relating to any Products, and all data contained in any of the foregoing, including all investigational new drug applications, Regulatory Approvals, regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.
- 1.70. **"Research Activities"** means all those tests, studies and other activities described in the Research Plan, as such plan may be amended in accordance with Section 2.4.
- 1.71. **"Research Documentation"** means any and all documents, records, accounts, notes, reports and other data documenting Research Activities, whether in written, electronic, video or other form.
- 1.72. "Research Plan" means a detailed research plan, describing the Research Activities to be performed, timelines to be adhered to and setting out in more detail the roles and responsibilities of each Party in connection with the Research Program, as may be amended pursuant to Section 2.4. The Research Plan shall include the activities outlined in Schedule 1. The Research Plan shall contain success criteria to be achieved and Deliverables to be provided for each Phase.

- 1.73. **"Research Program"** means the collective set of Research Activities to be conducted by the Parties in accordance with the Research Plan.
- 1.74. "**Results**" means any ideas, inventions, discoveries, know-how, data, documentation, reports, materials, work product, writings, designs, computer software, processes, principles, methods, techniques and other information, recorded in any form, that are identified, invented, discovered, conceived or reduced to practice in the conduct of the Research Program, other than the Bioinformatic Results.
- 1.75. "[\*\*\*] Cell Line" means the [\*\*\*] cell line ([\*\*\*] line [\*\*\*] developed by Universal from the [\*\*\*] Cell Line as such cell line exists prior to any editing by either Party.
- 1.76. "Sublicenses" shall mean the sublicenses executed between the Parties and in the agreed form set out in Schedules 2 and 3.
- 1.77. **"Sublicensed IP"** means the Intellectual Property Rights sub-licensed to Adaptimmune under the Sublicenses.
- 1.78. "TCR" means T-cell receptor.
- 1.79. "**Term**" has the meaning set forth in Section 15.1.
- 1.80. "Third Party" means any Person not including any of Universal or Adaptimmune or any of their respective Affiliates.
- 1.81. "**Third Party Claim**" has the meaning set forth in Section 14.1.
- 1.82. "**Trademark**" means any word, name, symbol, colour, designation or device or any combination thereof for use in the course of trade, including any domain name, trademark, trade dress, brand mark, trade name, brand name, logo or business symbol used by Adaptimmune and/or its Affiliates in connection with the Products.
- 1.83. "Universal IP" shall mean the Universal Know-How and Universal Patent(s).
- 1.84. "Universal Know-How" means all Information owned or Controlled by Universal at the Effective Date or during the term of this Agreement which may be necessary and/or useful for either (a) performance of the Research Program; (b) use of any work product (including Results) resulting from the Research Program; or (c) use of the BioInformatic Results as provided in Section 2.7.
- 1.85. **"Universal Material"** means Materials provided by Universal to Adaptimmune for use in the performance of the Research Program.
- 1.86. "Universal Patent(s)" means any Patents or other Intellectual Property Rights owned or Controlled by Universal at the Effective Date or during the term of this Agreement which may be necessary and/or useful for any of (a) performance of the Research Program; or (b) use of any work product (including Results) resulting from the Research Program;; or (c) use of the BioInformatic Results as provided in Section 2.7. The Universal Patents

shall include those patents and patent applications listed in Schedule 4 ("Universal Pre-existing Patents").

- 1.87. "Universal Technology" means Universal's rights to Gene Editing Technology and HLA Engineering Technology existing prior to the Effective Date or first conceived or first generated or first reduced to practice outside of the performance of the Research Program together with any improvements or developments to such technology made by Universal in the course of the Research Program, in each case which is used or incorporated in the Research Program (including any process used for manufacture or development of any work product).
- 1.88. "Valid Claim" means a claim of an issued and unexpired patent or patent application within the Universal Patents or Universal Know-How (including any Arising IP solely owned by Universal but excluding other Arising IP) to the extent that such claim in any patent or patent application has not lapsed, been withdrawn or been disclaimed, denied or admitted to be invalid in any court of competent jurisdiction or patent office in a non-appealable judgment or otherwise rendered invalid or unenforceable through reissue, disclaimer or otherwise or otherwise been cancelled or abandoned or dedicated to the public.

#### 2. Research Program

- 2.1. <u>Research Plan.</u> The Parties agree to perform the Research Activities for each Phase of the Research Plan as outlined in Schedule
- 2.2. <u>Research Activities</u>. Adaptimmune and Universal shall collaboratively conduct the Research Activities in accordance with the Research Plan. Notwithstanding the foregoing, each Party shall be responsible for performance of any Research Activities allocated to it under the Research Plan.
- 2.3. <u>Time for performance</u>. Both Parties shall use commercially reasonable efforts to perform their Research Activities in accordance with any timescales set out in the Research Plan. In addition Universal shall use commercially reasonable efforts to facilitate timely completion or performance of Research Activities where subcontracted to Third Parties and shall not prioritise the resourcing of other programs of work or research at Universal over the performance of the Research Program. Where any Research Activities are specified to be performed by Universal in the Research Plan and Universal is either unable to perform such Research Activities or alternatively is delayed in the start of performance of such Research Activities by over ninety (90) days, in addition to any other remedies available to it, Adaptimmune may [\*\*\*]. If, after any such inability to perform, Universal is able to perform, then Universal shall have the right to resume carrying out such Research Activities save to the extent such Research Activities [\*\*\*].
- 2.4. <u>Research Plan amendments.</u> The JSC shall review, revise as necessary and approve the initial Research Plan within forty five (45) days after the Effective Date. The Research Plan may only be amended through mutual agreement of the Parties.
- 2.5. <u>Conduct of Research Activities</u>. Each Party shall diligently perform or cause to be performed its Research Activities in good scientific manner and in compliance in all material respects with all Applicable Laws, including good laboratory practice and good clinical practices to the extent applicable.

- 2.6. <u>Laboratory Notebooks</u>. Universal shall use all reasonable endeavours to procure that its employees and any of its Third Party subcontractors shall keep and securely retain laboratory notebooks recording all Results. Such laboratory notebooks should reflect the chronological events and be witnessed. No attempt shall be made to falsify, amend or otherwise change notebooks that would in any way distort or change such record. Universal shall make all relevant pages of laboratory notebooks available at reasonable times upon reasonable notice for review, analysis and use by or on behalf of Adaptimmune during the performance of the Research Program and for a period of 6 years after expiry or completion of the Research Program or earlier termination of this Agreement. If Adaptimmune requires access to the whole laboratory notebooks for any reason, including in relation to litigation, then Universal shall make such notebooks available and the Parties will agree reasonable steps to preserve the confidentiality of their contents and in particular in respect of any records or laboratory notebooks created prior to the Effective Date, preservation of any confidential information owned or Controlled by any Third Party.
- 2.7. Research Results. During the Term, Universal shall promptly provide Adaptimmune with a copy of any Results and all raw data and other information that it has obtained in the conduct of the Research Program, in sufficient written detail to permit Adaptimmune to analyse such Results and employ them in its own Research Activities, for Exploitation of any Product or associated research, development and clinical programs in the Field, subject to Section 2.13. Adaptimmune will also share the Results it obtains during the conduct of the Research Program as required for the performance of the Research Program and otherwise by providing a project summary of its Research Activities to JSC meetings and Universal may request reasonable further clarification on the Results described in such project summary. Results, excluding any Arising IP in such Results which shall be owned by the Parties in accordance with the provisions of Section 7 below, will be owned as between the Parties as follows:
  - 2.7.1 Results generated by either Party and solely relating to the [\*\*\*] Cell Line and [\*\*\*] Cell Line will be owned solely by Universal;
  - 2.7.2 Results generated by either Party and solely relating to the HLA Engineering Technology-Edited Cell Line will be jointly owned by the Parties in equal undivided shares, without a duty of accounting or requirement to obtain consent for exploitation thereof (directly or with or through Affiliates or Third Parties), subject to any limitations expressly provided below;
  - 2.7.3 Results other than those set out in Sections 2.7.1 2.7.2 above will be owned solely by Adaptimmune, subject to the remainder of this Section 2.7.
  - 2.7.4 In relation to the Results solely related to the HLA Engineering Technology-Edited Cell Line under Section 2.7.2 above, Adaptimmune shall be entitled to use such Results solely in the Field in the course of activities conducted within the scope of the licenses granted under Section 5. Astellas shall not transfer the Results solely relating to the HLA-Edited Cell Line to any Third Party or use in any collaboration with any Third Party

the Results solely relating to the HLA-Edited Cell Line within the Field unless explicitly agreed in writing by Adaptimmune.

- 2.7.5 To the extent that Universal creates and develops a master cell bank of the HLA Engineering Technology-Edited Cell Line as part of the Research Plan, on written request from Adaptimmune Universal will provide up to 10 vials of cell line from such master cell bank to Adaptimmune and will transfer such vials within 30 days of receipt of request from Adaptimmune. Adaptimmune will reimburse Universal for any out of pocket expenses incurred in transporting such vials to Adaptimmune, such expenses to be mutually agreed.
- 2.7.6 Universal hereby grants to Adaptimmune the non-exclusive right to use any Results solely owned by Universal in accordance with Section 2.7.1 above for the Exploitation of any Product in the Field, excluding any Arising IP in such Results which shall be owned by the Parties in accordance with the provisions of Section 7 below and licensed as between the Parties in accordance with Section 5 below. Adaptimmune hereby grants to Universal the non-exclusive right to use any Results solely owned by Adaptimmune in accordance with Section 2.7.3 above for the exploitation of products outside the Field, excluding any Arising IP in such Results which shall be owned by the Parties in accordance with the provisions of Section 7 below and licensed as between the Parties in accordance with Section 5 below.
- 2.7.7 For clarity, Results excludes the BioInformatic Results; provided however that (a) Adaptimmune shall have the right to cross-reference any regulatory documents filed with regulatory authorities and Controlled by Universal that describe the generation of such Bioinformatic Results or analysis performed by Universal (or if relevant its Affiliates) to generate such Bioinformatic Results for any Product Exploited by Adaptimmune and Universal will provide such letter of cross-reference within 14 days of request from Adaptimmune; and (b) to the extent that Universal has not filed the necessary regulatory documents or information required by regulatory authorities in relation to any Bioinformatic Results or a right of cross-reference is not available, Universal will file such information or documents direct with the regulatory authority (including responding to questions or requests for clarification from such regulatory authority) or provide such information to Adaptimmune to enable Adaptimmune to file such information or documents with the relevant regulatory authority, as Universal elects in its sole discretion, within 30 days of written request from Adaptimmune or such other timeframe communicated by the relevant regulatory authority.

- 2.7.8 In addition, in the event of the commencement of a bankruptcy proceeding by or against Universal under the U.S. Bankruptcy Code, and in the event this Agreement is rejected by or on behalf of Universal in such proceeding, notwithstanding the provisions of this Section 2.7.8 and in addition to the provision of Section 15.7 below, Adaptimmune shall have the right, at its expense, to a complete duplicate of (or complete access to, as appropriate) all Results and any other data or information required for any Regulatory Documentation and Laboratory Notebooks in Universal's control reasonably necessary or useful for Adaptimmune to comply with its obligations under Applicable Law (including filing obligations in relation to any regulatory approvals required for any Product) to the extent not already in Adaptimmune's possession.
- 2.8. <u>Electronic records.</u> The Parties will share and provide access to Results and where practicable Deliverables through the use of a secure electronic system or facility. Adaptimmune shall be responsible for the set-up and maintenance of such system. The Parties will provide the Results and Deliverables in a format suitable for uploading into the relevant electronic system or facility. Universal will maintain any passwords or passcodes provided by Adaptimmune to facilitate access to electronic facility as Confidential Information of Adaptimmune and shall not provide such passwords or passcodes to Third Parties or to employees who do not require access to the electronic facility for the purposes of the performance of the Research Program.
- 2.9. <u>Commercialisation Responsibilities.</u> Adaptimmune shall be solely responsible for:
  - 2.9.1 Following completion of the Research Program, the further development of Products and clinical trials in respect of them; and
  - 2.9.2 formulating regulatory strategy and for preparing, filing, obtaining and maintaining Regulatory Documentation, and all Regulatory Approvals including, where applicable: (a) pricing or reimbursement approvals; (b) pre- and post-approval marketing authorisations (including any prerequisite manufacturing approval or authorisation related thereto); (c) labelling approvals; and (d) technical, medical and scientific licenses for Products. Adaptimmune shall be the holder of all Regulatory Approvals for Products and shall have responsibility for interactions with Governmental Authorities with respect to Products.
- 2.10. <u>Debarment</u>. Universal agrees to inform Adaptimmune in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the United States Federal Food, Drug and Cosmetic Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Universal's or its Affiliates' knowledge, is threatened, relating to the debarment or conviction of Universal or any Person performing services hereunder on behalf of Universal.
- 2.11. <u>Subcontracting.</u> Universal will not subcontract any performance of its Research Activities or the Research Program to any Third Parties (including Third Party manufacturers, suppliers or research institutions) without the prior written consent of Adaptimmune,

which consent shall not be unreasonably withheld, conditioned or delayed. Adaptimmune may require such Third Parties to agree specific terms relevant to such subcontracting prior to such subcontractor being approved by Adaptimmune. In particular, no facilities, resources or employees of [\*\*\*] or any other state funded organisation or Institution ("together "State Resources") will be used in the performance of any Research Activities without the explicit prior written consent of Adaptimmune, except with respect to any fee-based services provided by the [\*\*\*] that are identified in the Research Plan and agreed to by Adaptimmune. Universal confirms and represents that any use of fee-based services from the [\*\*\*] in the performance of the Research Plan do not require the assignment or licensing of any Intellectual Property Rights first conceived in the performance of the Research Plan to the [\*\*\*]. Where such State Resources are agreed by Adaptimmune to be used, Adaptimmune reserves the right to negotiate any required agreement for the use of such State Resources directly with the relevant Third Party. Universal and Adaptimmune will cooperate and work together to agree any subcontracting terms with Third Parties, to the extent requested by Adaptimmune.

- 2.12. Third Party provision of Materials or Information. Where any part of the Research Program by Universal requires Universal to provide or facilitate access to any Third Party Information or Third Party Materials (including cell lines or cell materials or manufacturing services), such Third Parties shall be specified in the Research Plan and Adaptimmune shall be entitled, at its request, to be involved in discussions and negotiations with such Third Party. Any contractual obligations with such Third Party will be pre-approved by Adaptimmune to the extent they impose any obligations, liability, requirement for license under any Adaptimmune Controlled Intellectual Property Rights or restrictions on Adaptimmune's use of any Results or on the performance of the Research Program. The provisions of this Section 2.12 do not apply to procuring of the [\*\*\*] Cell Line by Universal or to any obligations under the [\*\*\*] Agreement which is instead governed by Section 2.13 below.
- 2.13. <u>Use of [\*\*\*] Cell Line, [\*\*\*] Cell Line and HLA Engineering Technology-Edited Cell Lines</u>. Universal shall use the [\*\*\*] Cell Line and [\*\*\*] Cell Line as the starting material to perform its obligations under the Research Plan. The HLA Engineering Technology-Edited Cell Lines shall constitute Deliverables for the purposes of this Agreement. Notwithstanding anything to the contrary in this Agreement or the Research Plan, the following terms and conditions shall apply to any use of the HLA Engineering Technology-Edited Cell Lines by or on behalf of Adaptimmune:
  - 2.13.1 The use of the HLA Engineering Technology-Edited Cell Lines by Adaptimmune is subject to (a) certain obligations owed to the [\*\*\*] under the [\*\*\*] Agreement, including Appendix A attached thereto (Notice to RECIPIENT), as well as (b) those obligations to [\*\*\*] pursuant to [\*\*\*] License Agreement as set forth in Schedule 8 to this Agreement (Partner Notice).
  - 2.13.2 For the purposes of this Section 2.13 the additional definitions set out in Appendix A attached to the [\*\*\*] Agreement and Schedule 8 shall apply and shall override any conflicting definition in this Agreement.
  - 2.13.3 [\*\*\*]

#### 3. Management of Research Program

- 3.1. Formation of Joint Steering Committee. The Parties shall establish a "Joint Steering Committee" or "JSC" (the "JSC") to oversee the Research Program. Each Party shall initially appoint three (3) representatives of such Party or its Affiliates to the JSC. The JSC may change its size from time to time by mutual consent of its members, provided that the JSC shall consist at all times of an equal number of representatives of each of Universal and Adaptimmune. Each Party may replace its JSC representatives at any time upon written notice to the other Party or may delegate performance to an alternative representative by written notice to the other Party where any representative cannot attend meetings or is unable to vote. The JSC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement), but with a maximum of three (3) per Party, to participate in the discussions and meetings of the JSC, provided that such participants shall have no voting authority at the JSC. The JSC shall have a chairperson who shall be selected by Adaptimmune. The role of the chairperson shall be to convene and preside at meetings of the JSC, to prepare and circulate agendas and to ensure the preparation of minutes, but shall have no additional powers or rights beyond those held by the other JSC representatives. Attendance of representatives of a Party at meetings (including any associated travel or accommodation costs) of the JSC shall be at the cost and expense of the relevant Party.
- 3.2. <u>Meetings</u>. The JSC shall meet every three calendar months during performance of the Research Program unless the Parties mutually agree in writing to a different frequency for such meetings or as reasonably necessary. Meetings may be held in person or by telephone as agreed by the JSC. The JSC shall cease following completion of the Research Program.
- 3.3. <u>Specific Responsibilities of the JSC</u>. The JSC shall be responsible for overseeing the activities of the Parties under the Research Program. In addition to its general responsibilities, the JSC shall in particular, without limitations:
  - (i) approve the Research Plan;
  - (ii) oversee the implementation of the Research Plan;
  - (iii) oversee the conduct of research according to the Research Plan;
  - (iv) decide on discontinuation of studies in the Research Plan;
  - (v) decide on possible additional studies in the Research Plan;
  - (vi) decide on possible amendment of scope of the Research Plan;
  - (vii) resolve possible non-scientific issues (e.g. logistics and financial) directly relating to the Research Plan;
  - (viii) facilitate the flow of Information between the Parties in relation to the Research Plan; and
  - (ix) perform such additional functions in relation to the Research Program as the Parties may jointly agree from time to

The JSC shall not have any authority to amend the terms of this Agreement or to amend the level of any Development Milestone or Product Milestone or to expand the Research Plan beyond the Field.

- 3.4. Decision-Making of JSC. The JSC shall act by consensus. The representatives from each of (a) Universal and (b) Adaptimmune, will have, collectively, one (1) vote. If the JSC cannot reach consensus on an issue that comes before the JSC, then the Parties shall refer such matter to the CEO of Adaptimmune and the President of Universal (collectively, the "Senior Officers"). The Senior Officers shall use reasonable efforts to resolve such issue within thirty (30) days of the issue being referred to them. In the event that the Senior Officers cannot reach agreement, Adaptimmune shall have the casting vote to resolve such issue save where such issue would result in any of the following: (a) an increase in capital commitment for Universal which is not reimbursed by Adaptimmune; or (b) a material increase in resource commitment or financial commitment by Universal which is not reimbursed by Adaptimmune. Notwithstanding the foregoing, if there is a dispute as to whether a particular Phase of the Research Plan has been achieved (including without limitation for purposes of a Development Milestone being due), then Adaptimmune will not have the decision-making right and the Parties shall submit the dispute to an independent, neutral expert (mutually agreed in good faith) with biopharmaceutical expertise to determine whether the Phase or Development Milestone has been achieved. The Parties shall be bound by any such expert determination in the absence of manifest fraud and the non-prevailing Party shall pay the reasonable costs of such expert. Furthermore, notwithstanding the foregoing, any and all amendments to the Research Plan (including without limitation any decisions regarding discontinuation of studies or addition of possible studies in, or amendments of scope of, the Research Plan) shall require mutual written consent of the Parties, and shall not be subject to Adaptimmune's casting vote.
- 3.5. <u>Project Committee</u>. Day to day management of the Research Plan shall be carried out by a project committee comprised of at least one (1) project manager from each party. The Project Committee is a non-voting committee intended to facilitate collaboration between the parties and to manage performance of the Research Plan as against timescales set out in the Research Plan. The Project Committee shall meet on a regular basis at least monthly or as often as necessary to ensure management of the Research Program.
- 3.6. <u>Other Sub-committees</u>. Other sub-committees may be set up by the Parties from time to time during the Term in order to facilitate any particular Research Activities. The composition and scope of such sub-committees will be agreed by the JSC.

#### 4. Reports and Audits relating to the Research Program

4.1. Recordkeeping. Universal shall prepare and maintain complete, current, accurate, organized and legible records of all Research Documentation in a manner reasonably acceptable to Adaptimmune as necessary for patent and regulatory purposes and in full compliance with applicable UK and US law. All laboratory notebooks recording the Research Activities shall be dedicated to the Research Activities and not include any other research. Universal shall retain all Research Documentation and store such research Documentation securely for at least [\*\*\*] years from completion of such Research Documentation. Universal shall also maintain complete, current, accurate, organized and legible records of its work to generate the BioInformatic Results ("Additional Documentation"). Universal shall make all Research Documentation available at reasonable times upon reasonable notice for review by Adaptimmune, providing that such review shall be no more often than once per year. To the extent Adaptimmune requires

access to the Research Documentation or Additional Documentation after termination of this Agreement in order to comply with its obligations under Applicable Law, such access right shall continue to apply after termination of this Agreement. In other cases the right of access shall cease on termination of this Agreement. Universal shall notify Adaptimmune prior to any destruction of any Research Documentation and Additional Documentation and afford Adaptimmune the opportunity to take over storage of such Research Documentation or Additional Documentation.

- 4.2. Audits. To the extent required for Adaptimmune to satisfy its obligations under Applicable Law, Adaptimmune may audit Universal, no more than once in any calendar year, for compliance with Applicable laws. Adaptimmune shall provide at least 20 Business Days' notice of such requirement to audit. Universal will enable Adaptimmune or its designated Third Party inspector to carry out such audit including making all Research Documentation and Additional Documentation (if necessary) available, providing access to facilities used in the performance of the Research Program and providing access to relevant personnel in each case to the extent necessary for Adaptimmune to satisfy its obligations under Applicable Law. Universal will procure similar rights of access and audit from any Third Party sub-contractors it uses in the performance of the Research Program. To the extent Adaptimmune requires any audit after termination of this Agreement in order to comply with its obligations under Applicable Law, such audit right shall continue to apply after termination of this Agreement. In other cases the right of audit shall cease on termination of this Agreement.
- 4.3. <u>Governmental Authority inspection</u>. Universal will also permit any Governmental Authority to inspect its facilities and processes to the extent such Governmental Authority requires such inspection in relation to the performance of the Research Program or later supply and manufacture of Product by Adaptimmune. Universal will notify Adaptimmune if it receives any request for inspection by any Governmental Authority and provide Adaptimmune the opportunity to attend such inspection to the extent reasonable possible and in each case to the extent relevant to the Research Program or facilities used in the performance of the Research Program by Universal.
- 4.4. <u>Non-conformance</u>. Should any inspection (whether under Section 4.2 or 4.3) identify any non-conformance with Applicable Laws or other requirement, Universal shall promptly correct such non-conformance and shall keep Adaptimmune informed of the progress of such correction. Adaptimmune may carry out further inspections to assess the progress of such correction and to verify that any non-conformance has been corrected.

#### 5. Grant of Rights

5.1. <u>Licence Grants to Adaptimmune</u>. Universal hereby grants to Adaptimmune an exclusive, sub-licenseable, worldwide right and licence in the Field, with the right to grant sublicences, under the Universal Patents (excluding the Sublicensed IP) and Universal Know-how to use, sell, supply, manufacture (including to have manufactured), import, research, develop (including to have developed) and distribute (through multiple distribution levels) the Products. For clarity, (a) the foregoing license does not transfer any ownership of the Universal Patents, Universal Materials and Universal Know-how to Adaptimmune and (b) the foregoing license under the Universal Patents and Universal Know-How does not include, and Universal does not grant to Adaptimmune under this

Agreement, any sublicense under any patent or other Intellectual Property Rights Controlled by [\*\*\*] or by [\*\*\*].

- 5.2. <u>Diligence Obligations.</u> Other than as provided under the Research Plan or explicitly otherwise provided in this Agreement, Adaptimmune shall be solely responsible for the Exploitation of the Products in its sole discretion. Adaptimmune shall use Commercially Reasonable Efforts to further develop and to seek Regulatory Approval and to commercialise at least one Product. Save as explicitly provided in this Section 5.2, Universal acknowledges and agrees that nothing in this Section 5.2 is intended, or shall be construed, to require Adaptimmune to Exploit a specific Product providing that if Adaptimmune decides to discontinue the development of one Product in favour of another Product its obligations under this Section 5.2 shall cease with respect to such discontinued Product in favour of such other Product. Save as provided in this Section 5.2, Adaptimmune shall have no other obligation, express or implied, to Exploit the Products. Notwithstanding the foregoing, if Adaptimmune (a) makes any decision to cease working on the development or Exploitation of any Product; or (b) has no good faith intent to further develop or Exploit any Product and ceases actively working on the development or Exploitation of any Product for a period of [\*\*\*] consecutive [\*\*\*], then upon written notice Universal shall have the right to terminate this Agreement.
- 5.3. <u>Limitation on Adaptimmune diligence obligations</u>. Universal acknowledges that Adaptimmune is in the business of developing, manufacturing and selling pharmaceutical products and nothing in this Agreement shall be construed as restricting such business or imposing on Adaptimmune a duty to market and/or sell and exploit the Products to the exclusion of, or in preference to, any other product or process, or in any way other than in accordance with its normal commercial practices and those of its Affiliates.
- 5.4. <u>Sublicences.</u> Adaptimmune and Universal agree to enter in to the Sublicenses, approved versions of which are attached in Schedules 2 and 3. Both Parties shall execute such Sublicenses on the Effective Date.
- 5.5. <u>Licence Grant to Universal.</u> Adaptimmune grants to Universal a non-exclusive, non-transferable licence in the Field, without the right to grant sublicenses, under its Intellectual Property Rights to the extent necessary for Universal to perform its obligations under the Research Program. The licence granted under this Section 5.5 will terminate on completion of all Research Activities delegated to Universal under the Research Plan.
- 5.6. <u>Licence Grant for [\*\*\*].</u> Adaptimmune also grants to Universal a non-exclusive license under the [\*\*\*] solely to the extent required under the [\*\*\*]. Such license is not intended to give Universal any additional rights or licenses over and above those provided in Section 5.5 above.

#### 6. Consideration

6.1. <u>Effective Date Payment</u>. In partial consideration of the licenses and other rights granted by Universal to Adaptimmune herein and subject to the terms and conditions of this Agreement, Adaptimmune shall pay the sum of two and a half million US Dollars

(US\$2,500,000) to Universal within ten (10) Business Days of the Effective Date subject to receipt of an invoice from Universal.

6.2. <u>Development Milestones</u>. On achievement of the milestones set out below ("**Development Milestones**"), Adaptimmune shall pay the following payments to Universal, whether such milestones are first achieved by Universal or Adaptimmune:

(1) Approval of Phase 1 of the Research Plan by the JSC and completion of first project committee meeting:	US\$3,000,000
(2) [***]	US\$[***]
(3) [***]	US\$[***]
(4) [***]	US\$[***]
(5) [***]	US\$[***]
(6) [***]	US\$[***]
(7) [***]	US\$[***]

If any of the Development Milestones require a decision by the JSC or Adaptimmune, the JSC or Adaptimmune (as applicable) shall provide their decision within either (a) where any delivery criteria agreed for any deliverable require characterisation of such deliverable by Adaptimmune or performance of testing on any such deliverable, as soon as reasonably possible and in any event within ninety (90) days following applicable event first coming up for consideration; or (b) where no characterisation or testing is required, thirty (30) days after the applicable event first comes up for consideration. If the JSC or Adaptimmune (as applicable) does not decide to move to the next Phase or does not provide its approval or acceptance, then upon Universal providing thirty (30) days written notice and unless there is mutual agreement by the Parties otherwise this Agreement shall terminate. For the purposes of interpreting the Development Milestones above: [\*\*\*] Cell Bank ("MCB") of a B2M-edited, pluripotent Universal Donor Cell ("UDC") line engineered to prevent cell surface expression of polymorphic HLA class I molecules and with mutations in the RFXANK gene to prevent HLA-class II expression and as further defined in the Research Plan; "TCA-UDC" shall mean a T-cell adapted UDC line engineered to express a specific TCR or TCR variant with further mutations to prevent the expression of the endogenous TCR; "WCB" shall mean a Working Cell Bank.

6.3. <u>Modifications to Development Milestones</u>. The Parties accept that the above milestones are based on the Research Program as outlined in Schedule 1 and reflect reimbursement of the anticipated development expenses undertaken by Universal. Where the scope of such Research Program materially changes or requires Universal to take on a materially higher resource or financial burden, the Parties shall negotiate adjustment to the above Development Milestones in good faith to reflect such increased scope, resource or financial burden.

- 6.4. Adjustments to Development Milestones. Where any Research Activities are specified to be performed by Universal in the Research Plan and Universal is unable to perform such Research Activities or alternatively is delayed in the start of performance of such Research Activities and in accordance with Section 2.3 Adaptimmune takes over the performance of such Research Activities or appoints a Third Party to carry out such Research Activities, the Development Milestone will be reduced on a prorated basis to reflect the reduction in work activities being conducted by Universal. Where a Third Party is used by Adaptimmune to perform such Research Activities the reduction shall additionally cover the costs of such Third Party performing the Research Activities where greater than the pro-rated reduction in level of Development Milestone. Where no activities are performed by Universal under a Development Milestone as a result of an inability to perform by Universal, no Development Milestone shall become due and owing on achievement of such milestone by Adaptimmune.
- 6.5. <u>Product Milestones</u>. Adaptimmune shall pay the following product milestone payments on the first Product to achieve each of the following milestones ("**Product Milestones**"):



In this Section 6.5: (a) a "**Pre-Existing Adaptimmune Product**" shall mean a Product which comprises a sequence for a TCR and in relation to which Adaptimmune has previously received Regulatory Approval for a product comprising the same TCR sequence or a non-material variant of such TCR sequence; (b) a "**New Adaptimmune Product**" shall mean a Product comprising a sequence for a TCR and in relation to which Adaptimmune has not previously received Regulatory Approval or filed an IND (or foreign equivalent) for a product comprising the same TCR sequence or a non-material variant of such TCR sequence.

- 6.6. <u>Notice</u>. Adaptimmune shall give Universal written notice within twenty (20) Business Days of the first achievement of each milestone event set forth in Sections 6.2 (to the extent Universal is not already aware of achievement) and 6.5 above. After receiving such written notice, Universal shall submit an invoice to Adaptimmune for the amount of such milestone payment, and Adaptimmune will pay Universal the applicable milestone payment within thirty (30) days after receipt of an invoice from Universal.
- 6.7. One-Time Payments. Each individual milestone payment (whether a Development Milestone or Product Milestone) is payable one time only regardless of the number of Products developed and/or commercialized and regardless of the number of times any of the applicable events occurs with respect to any Product. Where any milestone event is not achieved the relevant Product Milestone or Development Milestone shall not be due and owing.

- 6.8. <u>No Additional Milestones</u>. In addition and for the avoidance of doubt, Adaptimmune will not be obligated to make any other payments in respect of the above milestone events to Universal and/or Third Parties.
- 6.9. <u>Profit Share</u>. Following expiry of the first [\*\*\*] period after First Commercial Sale of the First Multi-Indication Product by Adaptimmune its Affiliate or sublicensee, Adaptimmune will calculate the profit share due to Universal in relation to the commercialisation of such First Multi-Indication Product. The profit share for such [\*\*\*] period, and each consecutive [\*\*\*] period (each a "Profit Share [\*\*\*]") until expiration of the last Valid Claim, shall be calculated as follows:

\*\*\*

The New Mean Average Cost of Supply shall be the [\*\*\*] over the [\*\*\*] of sale for the [\*\*\*] sold by Adaptimmune or its Affiliate or sublicensee, the first month starting on date of First Commercial Sale of such Product.

The Old Mean Average Cost of Supply shall be the [\*\*\*] for the product sold by Adaptimmune or its Affiliate or sublicensee [\*\*\*] as used in the [\*\*\*] as calculated using the [\*\*\*] immediately preceding date of First Commercial Sale of the First Multi-Indication Product. [\*\*\*].

The Profit share due and payable shall be calculated in US dollars. Where any calculation of Mean Average Cost of Supply requires conversion from a currency other than US dollars, Adaptimmune shall carry out such conversion using Adaptimmune's customary and standard internal exchange rates. Where the Old Mean Average Cost of Supply is lower than the New Mean Average Cost of Supply, no profit share shall be payable.

If the Profit Share Amount is negative, then the First Multi-Indication Product shall be subject to the royalty under Section 6.12 and no further Profit Share shall be payable or owing from Adaptimmune.

- 6.10. <u>Valid Patent limitation</u>. The profit share payable in accordance with Section 6.9 above shall only be payable on Products which are Covered by a Valid Claim. Once the last Valid Claim to Cover the First Multi-Indication Product expires, any obligation to pay the profit share in relation to such Product shall cease. Except as set forth in the last paragraph of Section 6.9, for clarity no royalty shall be payable on the sale of a First Multi-Indication Product.
- 6.11. <u>Profit Share report</u>. Adaptimmune will deliver to Universal a report detailing the profit share due to Universal and calculated in accordance with Section 6.9 within sixty (60) calendar days of the expiry of each Profit Share [\*\*\*]. Adaptimmune will pay the relevant profit share to Universal following receipt of invoice from Universal and within 30 days of receipt of such invoice.
- 6.12. <u>Royalties</u>. In addition to the profit share payable under Section 6.9, on a country by country and Product by Product basis and for all Products other than the First Multi-Indication Product (unless subject to a royalty pursuant to the last paragraph of Section

- 6.9), Adaptimmune shall pay to Universal a royalty of [\*\*\*]% of Net Sales. Adaptimmune's obligation to pay royalty with respect to any Product shall commence upon the First Commercial Sale of a Product in a country and shall expire on the earlier of (i) the expiration of the last Valid Claim to Cover such Product; and (ii) the date that is [\*\*\*] years from the First Commercial Sale of such Product in a country ("**Royalty Term**"). On expiration of the Royalty Term in relation to any Product, no further royalties shall be due or payable in relation to the sale of such Product.
- 6.13. <u>Currency Conversion for Net Sales</u>. With respect to sales of Product in US dollars, the Net Sales shall be expressed in US dollars. With respect to sales of Products in a currency other than US dollars, the Net Sales shall be reported in US dollars and converted using Adaptimmune's customary and standard internal exchange rates. The basis of any conversion shall be specified in the relevant Royalty Report.
- 6.14. Royalty Reports. Following First Commercial Sale of a Product other than the First Multi-Indication Product, Adaptimmune shall provide a report to Universal within [\*\*\*] of each calendar quarter ("Royalty Report"), the first such report being due within [\*\*\*] days after expiry of the calendar quarter in which the First Commercial Sale of a Product (excluding the First Multi-Indication Product unless subject to a royalty pursuant to the last paragraph of Section 6.9) is made. The Royalty Report shall include (a) the total Net Sales for each Product worldwide; and (b) calculation of the royalty due to Universal under Section 6.12 above. On receipt of such Royalty Report, Universal will provide an invoice for the royalty and Adaptimmune shall pay such royalty within 30 days of receipt of invoice.
- 6.15. <u>Interest.</u> Payments which are not made when due may bear interest as of the due date until the date the amount is effectively received on the account of Universal, at a rate of EURIBOR (12 months) plus [\*\*\*]% calculated on a weekly basis for every week that the payment is due but unpaid. Universal shall notify Adaptimmune prior to making any interest charge on any overdue payment, providing at least 5 Business Days prior notice.
- 6.16. <u>Mode of Payment.</u> All payments set forth in this Section 6 shall be remitted by wire transfer to a bank account as Universal may designate in writing.
- 6.17. <u>Currency</u>. All payments required under this Section 6 shall be made in U.S. Dollars.
- 6.18. <u>Taxes</u>.
  - 6.18.1 General. Universal alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be paid by Adaptimmune) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Adaptimmune shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold and shall reasonably assist Universal in obtaining any such deductions.
  - 6.18.2 <u>Indirect Taxes.</u> All amounts payable by Adaptimmune under this Agreement are stated exclusive of any Indirect Taxes, which Universal may be obliged to

charge. If any Indirect Taxes are chargeable in respect of any Payments, Adaptimmune shall pay such Indirect Taxes at the applicable rate in respect of such Payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by Universal in respect of those Payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If such amounts of Indirect Taxes are refunded by the applicable Governmental Authority or other fiscal authority to Universal subsequent to payment, the Party receiving such refund will transfer such amount to the paying Party within sixty (60) days of receipt. The Parties agree to reasonably cooperate to provide any information required by the Party pursuing a refund of Indirect Taxes paid.

- 6.19. Operating Licences. Each Party is solely responsible for payment required under any operating licences or permits including any required to perform its Research Activities in accordance with Applicable Laws.
- 6.20. <u>Records.</u> Adaptimmune shall keep and maintain records of its sales of Products in sufficient detail to enable Universal to verify the accuracy of Payments due from Adaptimmune and pursuant to an inspection under Section 6.21. Adaptimmune shall keep such records for a period of five (5) years from the end of the calendar year in which the relevant Product sales were made.
- 6.21. Inspections. Universal shall be entitled to appoint an independent third party qualified accountant or a person possessing similar professional status and associated with an independent accounting firm acceptable to the Parties to verify the level of Net Sales accounted for by Adaptimmune in accordance with Section 6.12 and the basis for the calculation of profit share in accordance with Section 6.9. Adaptimmune shall make its records available as set forth in this Section 6.21. The accounting firm shall enter into appropriate obligations with Adaptimmune to treat all information it receives during its inspection in confidence. Such audit right shall apply no more than once in any calendar year and shall only relate to the previous three (3) calendar year's records (to the extent not previously audited by Universal). The independent third party shall only be entitled to report to Universal as to whether or not the Net Sales of any Product or the calculation of Profit Share are materially accurate. Where any inspection identifies any shortfall in the Payments required to Universal, Adaptimmune shall make up such shortfall within 30 days of receiving notice of such shortfall. Where any inspection identifies an overpayment in the Payments required to Universal, Adaptimmune shall be entitled to deduct the amount of such overpayment from the next Payment or Payments made to Universal. Universal shall pay the cost of any inspection unless such inspection identifies a shortfall in payments in the preceding calendar year in excess of five (5) percent in which case Adaptimmune shall pay the reasonable costs of the Third Party carrying out such inspection.
- 6.22. <u>Investment.</u> In addition to the above Payments, Universal shall provide Adaptimmune with the right to participate in the next two (2) Qualified Equity Investment Events that occur after the Effective Date, on the following terms:

- 6.22.1 If Universal proposes to conduct a Qualified Equity Investment Event, then it will provide Adaptimmune with as much notice as reasonably possible and in any event at least twenty (20) Business Days prior written notice of the estimated initial closing of such Qualified Equity Investment Event (a "Financing Notice"), which Financing Notice will also describe the principal terms of the Qualified Equity Investment Event.
- 6.22.2 If Adaptimmune wishes to participate in such Qualified Equity Investment Event, it must notify Universal within ten Business Days after delivery of the Financing Notice, in which case:
  - 6.22.2.1. Universal will allow Adaptimmune to participate in the initial closing of the Qualified Equity Investment Event;
  - 6.22.2.2. Universal will permit Adaptimmune to review the initial closing, such stock purchase agreement, investors' rights agreement, co-sale agreement, voting agreement and/or other agreements as are entered into by the investors in the Qualified Equity Investment Event generally ("Investment Documents") and both Universal and Adaptimmune will negotiate in good faith and on a timely basis any changes required by Adaptimmune to such Investment Documents; and
  - 6.22.2.3. Adaptimmune will execute and deliver to Universal at the initial closing, the agreed Investment Documents.

"Qualified Equity Investment Events" means a transaction or series of related transactions, conducted primarily for the purpose of raising additional working capital, in which Universal sells shares of its preferred stock to new or existing investors, other than to a Universal licensee or collaborator in connection with the grant of a license or entering into a collaboration.

Adaptimmune's rights and Universal's obligations under this Section 6.22 shall terminate on the earliest to occur of (a) the initial closing of the second Qualified Equity Investment Event occurring after the date of this Agreement, (ii) a Change of Control of Universal, or (iii) an initial public offering of Universal's common stock pursuant to a registration statement under the Securities Act of 1933, as amended.

Adaptimmune's agreement to participate in any such financing or investment shall be entirely at its discretion. The exact level of any contribution or financing shall be agreed as part of any financing round.

#### 7. Ownership of Intellectual Property

7.1. <u>Background Intellectual Property.</u> Nothing in this Agreement will affect the ownership of any Intellectual Property Rights and Patents Controlled by either Party prior to the Effective Date of this Agreement or arising outside of the performance of this Agreement or the Research Program.

- 7.2. <u>Ownership of Arising IP</u>. Any Intellectual Property Rights arising from the performance of the Research Program shall be owned as follows:
  - 7.2.1 All Arising IP which relates solely to the differentiation of T-cells or to any process relating to such differentiation or which is specific to the Field shall be solely owned by Adaptimmune.
  - 7.2.2 All Arising IP which is solely created or reduced to practice by Adaptimmune employees or employees of its Affiliates or by Third Parties on behalf of Adaptimmune or its Affiliates shall be solely owned by Adaptimmune.
  - 7.2.3 Excluding any Arising IP which is owned by Adaptimmune in accordance with Sections 7.2.1 and 7.2.2 above, any Arising IP which constitutes an improvement to or development of Gene Editing Technology or HLA Engineering Technology or which solely relates to the [\*\*\*] Cell Line or [\*\*\*] cell line shall be solely owned by Universal.
  - 7.2.4 Any Arising IP other than that owned in accordance with Sections 7.2.1 7.2.3 shall be jointly owned by Universal and Adaptimmune with each party having an undivided joint ownership interest in all rights, title and interest worldwide in and to such jointly owned Arising IP.
  - 7.2.5 Notwithstanding the foregoing, any Arising IP which relates solely to the HLA-Edited Cell Line shall be jointly owned by Universal and Adaptimmune with each party having an undivided joint ownership interest in all rights, title and interest worldwide in and to such jointly owned Arising IP.
  - 7.2.6 Subject to Section 7.4, with respect to jointly owned Arising IP, each of the parties shall have, and does hereby have an undivided joint ownership interest in all rights, title, and interest worldwide in and to such jointly owned Arising IP. Each party shall have the right to practice, license and sublicense (through multiple tiers), or otherwise exploit such jointly owned Arising IP without the consent of or accounting to the other Party, except as otherwise expressly set forth in this Agreement.
- 7.3. Assignment. At the request of Adaptimmune, Universal shall and shall procure that any of its employees, agents and contractors shall do all acts and things (including making declarations, oaths and providing assistance in relation to the supply of information for any patent applications) and execute all documents that may be reasonably necessary under the laws of any country for ensuring that all rights in Arising IP owned by Adaptimmune under Section 7.2.1 above are assigned to Adaptimmune together with the right to sue for past infringement and to recover damages. At the request of the other Party, each Party shall and shall procure that any of its employees, agents and contractors shall do all acts and things (including making declarations, oaths and providing assistance in relation to the supply of information for any patent applications) and execute all documents that may be reasonably necessary under the laws of any country for ensuring that all rights in Arising IP co-owned by it under Section 7.2.4 are vested in it in accordance with Section 7.2.4. Universal shall ensure that it has in place with all Third

Party subcontractors agreements assigning or requiring the assignment of any Arising IP to Universal sufficient to vest title to Arising IP in the relevant Party in accordance with Section 7.2 above. At the request of Universal, Adaptimmune shall and shall procure that any of its employees, agents and contractors shall do all acts and things (including making declarations, oaths and providing assistance in relation to the supply of information for any patent applications) and execute all documents that may be reasonably necessary under the laws of any country for ensuring that all rights in Arising IP owned by Universal under Section 7.2.3 above are assigned to Universal together with the right to sue for past infringement and to recover damages. Adaptimmune shall ensure that it has in place with all Third Party subcontractors, agreements assigning or requiring the assignment of any Arising IP to Adaptimmune sufficient to vest title to Arising IP in the relevant Party in accordance with Section 7.2 above.

- 7.4. <u>Jointly-owned IP</u>. To the extent that any Arising IP is jointly owned by the Parties under Section 7.2.4 and 7.2.5, then save as provided under Section 5.1 or this Section 7.4, both Parties shall be entitled to use such jointly owned Arising IP without restriction. Neither Party shall be entitled to assign its interest in such jointly owned Arising IP without the consent of the other Party save that either Party shall be entitled to assign its interest to an Affiliate or to an assignee to this Agreement (in accordance with Section 17). Both Parties shall be entitled to sub-license their interest in such jointly owned Arising IP without the requirement of consent from the other Party and in each case subject to the licences granted under Section 5.1. Universal shall not be entitled to use the jointly owned Arising IP under Section 7.2.5 within the Field (including to sub-license or license its interest within the Field) without the prior written consent of Adaptimmune.
- 7.5. <u>Sublicensed IP</u>. The Sublicensed IP will be licensed to Adaptimmune in accordance with the terms of the Sublicenses. Universal agrees that it shall notify Adaptimmune prior to any amendments to the terms of the AAC/HLA-engineering Licence or the Elf Licence. Such notification shall include the detail of the amendment proposed. Universal shall not agree any amendment that would adversely affect Adaptimmune's rights unless Adaptimmune provides its prior written consent to such amendment.

#### 8. Prosecution and Maintenance of patents

- 8.1. <u>Pre-existing Intellectual Property Rights.</u> Nothing in this Agreement will affect the prosecution and maintenance of any Intellectual Property Rights and Patents Controlled by either Party prior to the Effective Date of this Agreement or arising outside of the performance of this Agreement or the Research Program unless explicitly otherwise provided.
- 8.2. Prosecution of Arising IP. Adaptimmune shall be entitled in its sole discretion to control and take decisions in relation to the filing, prosecution, maintenance and obtaining, (including carrying out any interferences, reissue proceedings and reexaminations), throughout the world of any patent application Covering any Arising IP solely or jointly owned by Adaptimmune and all Patents granted therefrom at its expense and save as provided further below. Adaptimmune shall keep Universal reasonably informed through the JSC (to the extent still in existence or otherwise by notice in writing) of any filings of patent applications Covering any such Arising IP and the progress of such patent applications. Universal shall provide all necessary powers of attorney to Adaptimmune to allow Adaptimmune to carry out such prosecution and maintenance. Universal shall

be entitled in its sole discretion to control and take decisions in relation to the filing, prosecution, maintenance and obtaining, (including carrying out any interferences, reissue proceedings and re-examinations), throughout the world of any patent application Covering any Arising IP solely owned by Universal and all Patents granted therefrom at its expense. In relation to any patent applications covering any jointly owned Arising IP under Section 7.2.5, such patent applications shall be drafted jointly by the Parties and advisers for each Party shall work closely to ensure alignment on the contents of such patent applications. Any patent application filing shall require the approval of both Parties prior to filing. Adaptimmune will file and prosecute any mutually approved patent application but shall keep Universal fully informed of the prosecution of such patent applications and Patents granted therefrom. The parties shall cooperate to coordinate same-day Patent application filings for Arising IP, as requested by the other party, for any provisional or nonprovisional patent applications (but for clarity not any continuations, continuations-in-part or divisionals) as for Patent application filings within the Universal Cells Background IP or Adaptimmune Background IP that are directed to subject matter inventions that were used to identify, produce or develop a Product during the performance of activities under this Agreement to avoid jeopardizing patentability of any such Patent.

- 8.3. <u>Support.</u> Universal shall provide reasonable support in relation to Adaptimmune's prosecution and maintenance of any patent applications or Patents Covering the Arising IP solely or jointly owned by Adaptimmune, subject to reimbursement of out of pocket expenses that Universal necessarily incurs in providing such support. Adaptimmune shall provide Universal with updates (at the JSC or on the occurrence of any material event in relation to any Patent) in relation to the progress of any patent application or Patent claiming any such Arising IP.
- 8.4. <u>Election not to Prosecute.</u> If, Adaptimmune or Universal (each a "**Prosecuting Party**") elects not to pursue or continue the filing, prosecution (including any interferences, reissue proceedings and re-examinations) or maintenance of any Patent Covering any Arising IP solely or jointly owned by Adaptimmune or Universal respectively in any Major Territory, the relevant Prosecuting Party shall so notify the other Party promptly in writing in sufficient time (usually 45 days but may be a shorter period depending on the notice given to Prosecuting Party by the relevant patent office) in advance to enable other Party to meet any deadlines by which an action must be taken to establish or preserve any such rights in such notified Patent. Upon receipt of any such notice from Prosecuting Party and to the extent possible under any Third Party agreement existing as at the Effective Date, the non-Prosecuting Party shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution (but excluding any interferences, reissue proceedings and re-examinations) or maintenance, of such notified Patent, at its expense in such country. The non-Prosecuting Party will keep the Prosecuting Party reasonably informed with regard to the current status of any Patent for which non-Prosecuting Party takes over responsibility for under this Section 8.4, including providing copies of any material correspondence with relevant patent offices.
- 8.5. <u>CREATE Act.</u> Notwithstanding anything to the contrary in this Section 8 no Party shall have the right to make an election under the Cooperative Research and Technology

Enhancement Act of 2004, 35 U.S.C. 103(c)(2)-(c)(3) (the "CREATE Act") when exercising its rights under this Section 8 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

### 9. Enforcement of Patents

- 9.1. <u>Rights and Procedures</u>. In the event that a Party is notified that a Third Party may be infringing any of the Arising IP, Universal Patents or Universal Know-How, such Party shall promptly notify the other Party in writing, identifying the alleged infringer (to the extent not in breach of any Third Party obligation of confidence) and the alleged infringement complained of and furnishing the information of which it has been notified.
  - 9.1.1 [\*\*\*]
  - 9.1.2 Save as provided in Section 9.1.1 and subject to Section 9.3 below, in relation to any other infringement or alleged infringement of a Patent within the Universal IP, Universal may, in its sole discretion and in its own name, through counsel of its choosing, take any measures it deems appropriate to stop such infringing activities by such Third Party in any part of the Territory or to grant to the infringing Third Party adequate rights and licenses necessary for continuing such activities. Any licences granted to any Third Party shall not restrict or conflict with the licences and rights granted to Adaptimmune under this Agreement.
  - 9.1.3 Upon reasonable request by the enforcing Party and at the enforcing Party's cost and expense, the other Party shall provide all reasonable information and assistance, including allowing access to files and documents and to personnel who may have possession of relevant information and, if necessary for prosecution of any legal action, joining in the legal action.
- 9.2. Recovery. Any amounts recovered by an enforcing Party pursuant to Section 9.1.1 (expressly excluding Section 9.1.3), whether by settlement or judgment, shall be shared as follows: the enforcing Party shall first reimburse its costs and expenses for the infringement action and retain [\*\*\*] ([\*\*\*]%) of the remainder and provide the non-enforcing Party with the remaining [\*\*\*] ([\*\*\*]%) of the remainder.
- 9.3. Enforcement of Sublicensed IP. Any enforcement of any Sublicensed IP shall be subject to the terms of the Sublicenses.

# 10. Potential Third Party Actions

10.1. Third Party Licenses. If, in the opinion of Adaptimmune, the Exploitation of the Products by Adaptimmune, its Affiliates or any of their licensees infringes or misappropriates any Patent or any Intellectual Property Right of a Third Party in any country, then, Adaptimmune shall have the right, but not the obligation to negotiate and obtain a license from such Third Party as necessary for Adaptimmune and its Affiliates and licensees to

Exploit the Products in such country. Adaptimmune will be responsible for the performance of any license agreement it executes with such Third Party. Adaptimmune understands and accepts that it shall be responsible for negotiation of any agreements with Third Parties required for the commercial use of any Third Party cell lines or cell banks required for commercial manufacture and sale of Product (excluding any use for research and development or clinical trials).

# 10.2. <u>Invalidity or Unenforceability Defences or Actions.</u>

- In the event that a Third Party asserts, as a defence or as a counterclaim in any infringement action, that any Universal Patent (excluding any Arising IP) or any Arising IP solely owned by Universal is invalid or unenforceable, then Universal shall have the right, but not the obligation, through counsel of its choosing to respond to such defence or defend against such counterclaim (as applicable), including the right to settle or otherwise compromise such claim.
- Similarly, if a Third Party asserts, in a declaratory judgment action or similar action or claim filed by such Third Party, that any Patent within the Arising IP solely or jointly owned by Adaptimmune is invalid or unenforceable, then Adaptimmune shall have the right, but not the obligation, through counsel of its choosing to defend against such action or claim.
- 10.3. <u>Third Party Litigation</u>. In the event of any actual or threatened suit against Adaptimmune or Universal alleging that the Exploitation of Products by or on behalf of Adaptimmune under this Agreement infringes the Patent or Intellectual Property Rights of any Person (an "Infringement Suit"), the Party first becoming aware of such Infringement Suit shall promptly give written notice to the other Party. In relation to any Products, Adaptimmune shall have the right, but not the obligation, through counsel of its choosing, to assume direction and control of the defence of claims arising therefrom (including the right to settle such claims in its sole discretion).
- 10.4. <u>Cooperation</u>. Each Party will provide to the other Party all reasonable assistance requested by such Party in connection with any action, claim or suit under Section 10.2 or 10.3, including allowing such Party access to the other Party 's files and documents and to the other Party 's personnel who may have possession of relevant information. The requesting Party shall pay the other Party's reasonable out of pocket expenses in relation thereto. In particular the other Party will promptly make available to the requesting Party, all information in its possession or control that it is aware will assist such Party in responding to any such action, claim or suit under Section 10.2 or 10.3.

# 11. Confidentiality and Non-Disclosure

11.1. <u>Confidentiality.</u> At all times during the term of this Agreement and for a period of [\*\*\*] years following termination or expiration hereof, each Party (the "**Receiving Party**") shall, and shall cause its officers, directors, employees, agents, Affiliates and sub-licensees to, keep confidential and not publish or otherwise disclose and not use, directly or indirectly, for any purpose, any Confidential Information of the other Party (the "**Disclosing Party**"), except to the extent such disclosure or use is otherwise expressly permitted or licensed by the terms of this Agreement.

- 11.2. Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:
  - 11.2.1 made in response to a valid order of a court of competent jurisdiction or other competent authority; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash any such order or obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in response to such court or governmental order;
  - 11.2.2 made by Adaptimmune or its Affiliates or its licensees to a Governmental Authority as may be necessary or useful in connection with any filing, application or request for a Regulatory Approval and or pricing or reimbursement approval, pre- and post-approval marketing authorisations (including any prerequisite manufacturing approval or authorisation related thereto), labelling approval and technical, medical and scientific licenses; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;
  - 11.2.3 made by a Party to a patent authority as may be necessary or useful for purposes of obtaining or enforcing a Patent (consistent with the terms and conditions of Sections 8 and 9); provided, however, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;
  - 11.2.4 otherwise required by Applicable Law or by stock exchange or other financial authority requirement;
  - 11.2.5 made by Adaptimmune or its Affiliates or its licensees to Third Parties as may be necessary or useful in connection with the Exploitation of Products, including subcontracting or sublicensing transactions in connection therewith and in each case subject to such Third Parties, where reasonably possible, agreeing confidentiality obligations substantially equivalent to those set out in this Agreement; or
  - 11.2.6 made by Universal or its Affiliates to actual or prospective investors or acquirers to the extent necessary for the purposes of such investment or acquisition and provided that in each such case investors or acquirers are subject to written obligations of confidentiality substantially equivalent to those set out in this Agreement.

Notwithstanding the foregoing, in the event that Adaptimmune or any of its Affiliates is required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body to disclose this Agreement, in whole or in part, the Parties shall reasonably agree on a redacted version of this Agreement as necessary to protect the Confidential Information of Universal prior to making such disclosure.

- 11.3. Exclusions. Notwithstanding the foregoing, Confidential Information shall not include any information that:
  - is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the Receiving Party;
  - 11.3.2 can be demonstrated by documentation or other competent proof to have been in the Receiving Party's or its Affiliates' possession prior to disclosure by the Disclosing Party;
  - is subsequently received by the Receiving Party or its Affiliates from a Third Party who is not bound by any obligation of confidentiality with respect to said information;
  - 11.3.4 is generally made available to Third Parties by the Disclosing Party without restriction on disclosure; or
  - is independently developed by or for the Receiving Party or its Affiliates without reference to the Disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

- 11.4. <u>Results</u>. Universal and Adaptimmune shall each keep the Results confidential as if such Results were Confidential Information of the other Party, save:
  - 11.4.1 To the extent such disclosure is permitted for Confidential Information under Section 11.2 above;
  - 11.4.2 to the extent such Results need to be disclosed to Third Parties (i) in the case of Universal for the further development of the Universal Technology outside of the Field provided that if the Results to be disclosed would include information regarding the Field, then where reasonably possible subject to such Third Party agreeing to obligations of confidentiality substantially equivalent to those set out in this Agreement; and (ii) in the case of Adaptimmune for the further development and Exploitation of Products within the Field and where

reasonably possible subject to such Third Party agreeing to obligations of confidentiality substantially equivalent to those set out in this Agreement;

- 11.4.3 to the extent such Results are published under Section 11.5;
- 11.4.4 to the extent the Results satisfy any of the exclusions under Section 11.3.
- 11.5. Publications and Presentations. The Parties acknowledge that scientific publications must be strictly monitored to prevent any adverse effect from premature publication of results of the research and development activities hereunder. Accordingly Universal shall not publish, present or otherwise disclose Confidential Information of Adaptimmune without the prior written consent of Adaptimmune which can be withheld in its absolute discretion. Where either Party wishes to publish any Results ("Publishing Party"), it shall provide the other Party with prior written notice of such, where reasonably possible such notice being provided at least 30 days prior to any deadline for submission of such publication. The non-Publishing Party shall be entitled to review and comment on the publication and to request removal of any Results which it considers would (a) place it in breach or non-conformance with any Applicable Law or any requirement of any stock exchange rules or requirements; (b) would invalidate or prevent the filing of any patent application or the prosecution of any existing patent application; or (c) would materially affect its commercial interests, ongoing development programs or development of its products or programs. The Publishing Party shall incorporate any reasonable comments made by the non-Publishing Party and shall remove any Results which non-Publishing Party requests removed pursuant to this Section 11.5. In relation to any Results which are specific to the Field or which relate to any clinical trial which Adaptimmune is controlling or sponsoring, Adaptimmune shall be entitled to decline the publication of any such Results in its sole discretion. In relation to any Results which do not relate to the Field, Universal shall be entitled to decline the publication of any Results in its sole discretion.
- 11.6. <u>Use of Name</u>. Neither Party, nor its Affiliates shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of another Party or its Affiliates in any publication, press release, promotional material or other form of publicity without the prior written consent of such other Party. The restrictions imposed by this Section 11.6 shall not prohibit a Party from making any disclosure identifying another Party that is required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body, provided that any such disclosure shall be governed by this Section 11. Further, the restrictions imposed on each Party under this Section 11.6 are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Section 11.
- 11.7. Public Announcements. No public announcement concerning this Agreement, its subject matter or the transactions described herein shall be made, either directly or indirectly, by Adaptimmune or Universal or their respective Affiliates, except as may be legally required by Applicable Laws, regulations, judicial order, or required by stock exchange or quotation system rule without first obtaining the approval of the other Party and agreement upon the nature, text and timing of such announcement, which approval and agreement shall not be unreasonably withheld or delayed. The Party desiring to make any such voluntary public announcement shall provide the other Party with a written copy

of the proposed announcement in reasonably sufficient time prior to public release to allow such other Party to comment upon such announcement, prior to public release. In the case of press releases or other public communications legally required, or required by stock exchange or quotation system rule, to be made, the Party making such press release or public announcement shall provide to the other Party a copy of the proposed press release or public announcement in written or electronic form upon such advance notice as is practicable under the circumstances for the purpose of allowing the notified Party to review and comment upon such press release or public announcement. Under such circumstances, the releasing Party shall not be obligated to delay making any such press release or public communication beyond the time when the same is required to be made in order to facilitate review and comment by the receiving Party.

### 12. Trademarks

12.1. Adaptimmune shall have the sole right to select the Trademarks for the marketing and sale of the Products; provided the Trademark is not a trade mark registered by Universal. Adaptimmune shall own such Trademarks and all Intellectual Property Rights and other rights and goodwill with respect thereto. Universal shall not, and shall not permit its Affiliates to, use any trademark that is the same as or confusingly similar to, misleading or deceptive with respect to or that dilutes any registered Trademark.

# 13. Representations, Warranties and Covenants

- 13.1. Universal represents and warrants to Adaptimmune as at the Effective Date that:
  - To its knowledge the University of Washington is the sole legal and beneficial owner of the Universal Pre-existing Patents and to its knowledge has obtained written assignments of all right, title and interest from the inventors named on the Universal Pre-existing Patents; ;
  - It is the sole and beneficial owner of any Universal Materials (excluding any intellectual property rights) or alternatively that it has the unencumbered right (excluding the [\*\*\*] License Agreement, and subject to Section 2.13) to provide any Universal Materials for use in the Research Program and in each case save as explicitly otherwise communicated in writing to Adaptimmune; except that the foregoing does not extend to ownership of the [\*\*\*] Cell Line, the [\*\*\*] Cell Line or [\*\*\*] Licensed Patents, or to the HLA Engineering Technology-Edited Cell Line as described in Section 2.13.
  - 13.1.3 It will have in place binding legal agreements with all of its employees and sub-contractors which assign and require the assignment of any Arising IP created or reduced to practice by employees or consultants of Universal or sub-contractors acting on behalf of Universal, to Universal;
  - 13.1.4 To its knowledge, the use of the Universal Technology in the performance of the Research Plan by Universal, excluding the loci and promoter, the sequences thereof and any other sequences provided by Adaptimmune and the use of the Gene Editing Technology to deliver those sequences to cells, will not infringe any Patent or other Intellectual Property Right or proprietary right of any Person subject in each case to compliance with the terms and conditions

- applicable to the use of the HLA Engineering Technology-Edited Cell Lines by or on behalf of Adaptimmune and as set out in Section 2.13:
- 13.1.5 It is not aware of any other individual who has made an inventive contribution to any of the inventions disclosed and claimed in the Universal Pre-Existing Patents other than those inventors named as inventors in the filing of such Universal Pre-Existing Patents.
- 13.1.6 The conception, development and reduction to practice of the Universal Know-How and Universal Patents has not, to Universal's knowledge, constituted or involved the misappropriation of trade secrets or other rights or property of any Person.
- 13.1.7 No claim or litigation has been brought or threatened as of the Effective Date by any Person alleging, and Universal is not aware of any possible claim, whether or not asserted, that Adaptimmune's use the Universal Patents and Universal Know-How would violate, infringe or otherwise conflict or interfere with any intellectual property or proprietary right of any Person.
- 13.1.8 Universal has not previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to the Universal Patents or Universal Know-How in the Field.
- 13.1.9 As of the Effective Date, and except with respect to amendments provided to Adaptimmune, no amendments have been agreed between Universal and the University of Washington to the terms of the Elf Licence or the AAV/HLA-engineering Licence.
- 13.1.10 Universal is not in breach of any of the terms of the AAV/HLA-engineering Licence or the Elf Licence, it has not received notice of any breach from the University of Washington and is not aware of any circumstances which would put it in breach of any term of the AAV/HLA-engineering Licence or the Elf Licence.
- 13.1.11 Universal has not entered into any agreement with any Third Party (whether oral or written) which would conflict with or restrict the rights and licences granted to Adaptimmune under this Agreement, save for the AAV/HLA-engineering Licence and the Elf Licence.
- 13.1.A Universal represents that as at the Amendment Date, it has not received any notice of any breach of the [\*\*\*] Agreement or [\*\*\*] License Agreement. Unless and until Adaptimmune [\*\*\*] and provided Adaptimmune does not [\*\*\*], Universal agrees that it will not (a) [\*\*\*]; or (b) [\*\*\*].
- 13.2. Each Party represents and warrants to the other Party that:
  - 13.2.1 it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

- 13.2.2 it has full legal power to grant the rights and licenses granted to the other under this Agreement; and
- 13.2.3 it has taken all necessary action on its part required to authorise the execution and delivery of this Agreement.
- 13.3. <u>DISCLAIMER OF WARRANTY.</u> EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN IN THIS AGREEMENT NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

For clarity, except as otherwise expressly provided in this Section 13, nothing in this Agreement shall constitute a representation or warranty of any kind with respect to [\*\*\*].

# 14. Indemnity and Limitation

- 14.1. Indemnification of Adaptimmune by Universal. In addition to any other remedy available to Adaptimmune, Universal shall indemnify, defend and hold harmless Adaptimmune, its Affiliates and their respective directors, officers and employees, from and against any and all Losses incurred by them to the extent resulting from or arising out of or in connection with any claims made or suits brought by a Third Party (collectively, "Third Party Claims") against Adaptimmune, its Affiliates or their respective directors, officers or employees that arise or result from (i)any claim that the use of the Universal Technology to produce the HLA Engineering Technology-Edited Cell Line in the course of the Research Program infringes the rights of any Third Party (provided that the foregoing expressly excludes any claim relating to any use of [\*\*\*]); or (ii) breach of any of the terms of this Agreement by Universal (or any Third Party acting on behalf of Universal); or (iii) breach of any Applicable Laws by Universal (or any Third Party acting on behalf of Universal) except for (x) any Loss for which Adaptimmune has an obligation to indemnify Universal and its Affiliates pursuant to Section 14.2, as to which Loss each Party shall indemnify the other to the extent of their respective liability for such Loss; or (y) caused by the gross negligence or wilful misconduct of Adaptimmune or its Affiliates; or (z) any use of the Universal Technology by Adaptimmune outside of the Field or within the Field in a manner or form differently from that provided for use in or used in the performance of the Research Program.
- 14.2. <u>Indemnification of Universal by Adaptimmune</u>. In addition to any other remedy available to Universal, Adaptimmune shall indemnify, defend and hold harmless Universal, its Affiliates, and its and their respective directors, officers and employees, from and against

any and all Losses incurred by them to the extent resulting from or arising out of or in connection with any Third Party Claims against Universal its Affiliates or its or their respective directors, officers or employees that arise or result from (i) any claim that use of the Adaptimmune Technology or any materials provided by or on behalf of Adaptimmune by Universal in the performance of the Research Program infringes the rights of any Third Party; (ii) any breach of Applicable Laws by Adaptimmune or its Affiliates or (iii) the development or commercialization of any Product by Adaptimmune, its Affiliates or sublicensees, or (iv) any use of the HLA Engineering Technology-Edited Cell Line by or on behalf of Adaptimmune, its Affiliates or sublicensees, including without limitation any use of the HLA Engineering Technology-Edited Cell Line for purposes not in compliance with Section 2.13, Schedule 8, except for any Loss (x) for which Universal has an obligation to Indemnify Adaptimmune and its Affiliates pursuant to Section 14.1, as to which Loss each Party shall indemnify the other to the extent of their respective liability for such Loss or (y) caused by the gross negligence or wilful misconduct of Universal.

- 14.3. Indemnification Procedure. Should the Indemnified Party intend to claim indemnification hereunder from the Indemnifying Party the Indemnified Party shall promptly notify the Indemnifying Party in writing of any Losses in respect of which the Indemnified Party intends to claim such indemnification and the Indemnifying Party shall be entitled, but not obligated, to assume the defence of any Third Party Claim thereof with counsel selected by it. The Indemnified Party, including its Affiliates, directors, officers and employees, shall co-operate fully, at the Indemnifying Party's expense, with the Indemnifying Party and its legal representatives in the investigation and defence of any Third Party Claim covered by this indemnification. The indemnification shall not apply to amounts paid in settlement of any Third Party Claim if such settlement is effected without the consent of the Indemnifying Party which consent will not be unreasonably withheld.
- 14.4. <u>LIMITATION ON DAMAGES</u>. EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE, DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF EITHER PARTY, OR FRAUD BY A PARTY OR ITS AFFILIATES, NO PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING INDIRECT LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE. EACH PARTY'S TOTAL AGGREGATE LIABILITY UNDER ANY INDEMNITY PROVIDED UNDER SECTION 14 OF THIS AGREEMENT SHALL BE LIMITED TO THE GREATER OF: (A) [\*\*\*].
- 14.5. Additional Limitation. Universal shall not be responsible for any Losses under the indemnity in Section 14.1 to the extent that any Third Party Claims (a) arise as a result of the commercial use of any cell line for which Adaptimmune has entered into an Agreement with a Third Party provider of such cell line for such commercial use; (b) arise as a result of the use by or on behalf of Adaptimmune or any of its sublicensees or third party sub-contractors of any HLA Engineering Technology-Edited Cell Line provided to Adaptimmune under this Agreement (except to the extent arising out of the practice by Universal of the Universal Technology used to produce such HLA Engineering Technology-Edited Cell Line, and not attributable to the loci and promoter,

the sequences thereof and any other sequences provided by Adaptimmune or the use of the Gene Editing Technology to deliver those sequences to cells); (c) arise as a result of any use by Adaptimmune of the Universal Technology outside of the scope of any licence agreement negotiated between Adaptimmune and the relevant Third Party or between Universal and the relevant Third Party (provided in the latter case Adaptimmune has reviewed and approved the terms of such Third Party license and excluding [\*\*\*] which are subject to Section 14.5(d) below); (c) relates to any part of the Product or part of the manufacturing process other than the Universal Technology; or (d) arise as a result of any breach by Adaptimmune of Section 2.13.

14.6. <u>Insurance</u>. Each Party shall have and maintain such type and amounts of liability insurance covering its liabilities under this Agreement as is normal and customary in the industry generally. The requirement to maintain insurance under this Section 14.6 shall not limit the liability of a Party under this Agreement.

### 15. Term and Termination of Agreement

- 15.1. <u>Term.</u> The term of this Agreement shall become effective as of the Effective Date and unless terminated earlier as provided herein (including pursuant to Section 5.2 or 6.2) shall continue until the last to expire of any Patent or other Intellectual Property Rights within the Universal Patents (the "**Term**").
- 15.2. <u>Termination by Adaptimmune</u>. Adaptimmune shall have the right, in its sole discretion, to terminate this Agreement by giving thirty (30) days' prior written notice to Universal (a) for safety or scientific reasons; (b) if a Third Party Patent is identified which would Cover any Product and a licence or alternative development route is not commercially feasible in Adaptimmune's sole discretion; or (c) in the event it does not wish to proceed with the next Phase of the Research Plan, based on the outcome of any previous Phase.
- 15.3. <u>Termination for Material Breach</u>. If either Party is in material breach of the Agreement (a "**Breaching Party**"), in addition to any other right and remedy the other Party (the "**Complaining Party**") may have, the Complaining Party may terminate this Agreement in its entirety by ninety (90) days prior written notice (the "**Notice Period**") to the Breaching Party, specifying the breach and its claim of right to terminate, provided always that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period (or, if such default cannot be cured within such ninety (90) day period, if the Breaching Party commences actions to cure such default within the Notice Period and thereafter diligently continues such actions).
- 15.4. <u>Termination for Insolvency</u>. Either Party may (without limiting any other remedy it may have), terminate this Agreement with immediate effect if the other Party becomes insolvent, is unable to pay its debts, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of a solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other Party's assets, or if the other Party makes any arrangement with its creditors or ceases to carry on business or does or suffers any similar or analogous act existing under the laws of any country.

# 15.5. <u>Consequences of Termination</u>

- 15.5.1 <u>Termination of Rights</u>. In the event of termination or expiry of this Agreement and save as otherwise explicitly provided all rights and licences granted to Universal and to Adaptimmune under this Agreement shall terminate and each Party shall return all data, files, records and other materials in its possession or control containing or comprising the other Party's Information or other Confidential Information to which such first Party does not retain rights hereunder (except one copy of which may be retained by the returning Party's General Counsel or external law firm solely for archival purposes).
- 15.5.2 <u>Licence of Adaptimmune Know How.</u> On expiry of the Term but not termination, Universal shall grant Adaptimmune a non-exclusive, royalty free, fully paid up, perpetual, irrevocable, worldwide, assignable right and licence in the Field, with the right to grant sublicences through multiple tiers, under the Universal Know How to Exploit and further develop the Products.
- 15.5.3 Return of Materials. On termination but not expiry (a) each Party will return any Materials of the other Party to that other Party promptly on termination, and (b) Adaptimmune and its Affiliates and sublicensees shall cease all use of the Deliverables (to the extent such Deliverables cannot be used without a licence under any of Universal's Intellectual Property Rights).
- 15.5.4 <u>Remedies</u>. Early termination of this Agreement by a Party shall in no way affect or limit such Party's right to claim against any of Universal, or Adaptimmune for any damages arising out of the breach of this Agreement.
- 15.6. Change of Control. Universal shall notify Adaptimmune of any Change in Control of Universal in advance of such Change in Control where possible or in any event within five (5) Business Days following such Change in Control. If the Change in Control occurs prior to completion of the Research Program, then when Adaptimmune receives notice of such Change in Control, if the surviving entity (excluding any Competitor) does not also provide a written notice within five (5) Business Days of such Change of Control that the surviving entity will assume the obligations of Universal and complete the Research Program, then: (a) Adaptimmune will have the option to terminate this Agreement immediately on written notice and the provisions of Section 15.5 above shall apply to such termination; or (b) Adaptimmune may elect by provision of notice in writing to Universal, in its sole discretion to perform additional parts of the Research Plan previously reserved to Universal. Where any Development Milestone was attributed to completion of such additional parts, such Development Milestone shall cease to be payable where Adaptimmune takes over performance of the relevant Research Activities. Where any part of the Research Plan or Phase of the Research Plan was part performed, following Adaptimmune taking over performance of such part or Phase of the Research Plan the Development Milestone for such part or Phase will be pro-rated accordingly based on the Research Activities performed prior to receipt by Universal of notification from Adaptimmune. Universal will cooperate with Adaptimmune to ensure that any handover of Materials and Information required for Adaptimmune to take over performance of Research Activities occurs promptly and Universal will make relevant

personnel available to ensure a smooth transition in such Research Activities. In the event of a Change in Control and Adaptimmune electing to take over the Research Plan in accordance with Section 15.6(b) or in the event of a Change in Control in favour of a Competitor the following shall apply:

- 15.6.1 The licences and rights granted by Adaptimmune to Universal shall immediately terminate save to the extent required to ensure a smooth transition of the Research Activities to Adaptimmune;
- 15.6.2 Any reporting obligations from Adaptimmune to Universal shall cease and save as necessary under Section 6 for the purposes of payment of the Development Milestones and Product Milestones, for the reporting and payment of Profit Share and Royalty. Adaptimmune shall be under no further obligation to continue to report on the progress of the Research Program or to share any results or development of any Deliverable or Product with Universal.
- Universal shall immediately (a) provide to Adaptimmune all Results generated to date including any Deliverables (even if not in final form) or otherwise provide access to such Results and Deliverables (in the case of cell lines, cell banks or other cell based deliverables or materials); and (b) to the extent any Research Activities are provided by a Third Party, provide access to such Third Party and facilitate an ongoing relationship between such Third Party and Adaptimmune to enable Adaptimmune to complete the Research Program in its sole discretion.
- 15.6.4 The licence rights and access reports granted to Adaptimmune shall continue in full force and effect for the Term.

  The diligence obligations under Section 5.2 shall continue to apply but for clarity, Adaptimmune shall be under no obligation to provide any reports on progress or any detailed reports on Product sales, nature of Product, manufacturing process for Product or timelines for Exploitation of any Product.
- 15.6.5 The JSC shall immediately cease as shall any project or other sub-committees save where such committees are required to facilitate transition of the Research Activities to Adaptimmune.
- 15.6.6 Other terms of the Agreement shall remain in full force and effect.

Pending notice of Change in Control under this Section 15.6 with a Competitor and termination or transfer of Research Program to Adaptimmune in accordance with this Section 15.6, Universal will not permit the Third Party Competitor (or any of its employees) in respect of which the relevant Change in Control has occurred to have access to any Confidential Information of Adaptimmune (other than Confidential Information permitted to be provided in accordance with Section 11 above).

15.7. **Application of US Bankruptcy Code**. The Parties agree that the license rights granted under this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and similar laws and regulations outside of the

United States, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code or such other laws and regulations. The Parties shall retain and may fully exercise all of their respective rights and elections under Section 365(n) of the Bankruptcy Code or similar laws and regulations outside of the United States. During the duration of the Research Program, Universal agrees to provide to Adaptimmune a copy of its audited accounts (or if not audited, its annual accounts or financial statements) within 30 days of finalisation, or alternatively the CEO of Universal will telephone the CEO of Adaptimmune within 30 days of annual accounts being finalised to discuss the contents of the annual accounts and in particular financial status of Universal.

### 15.8. <u>Accrued Rights; Surviving Obligations</u>.

Survival. The termination of this Agreement shall not relieve any of Universal or Adaptimmune from performing any obligations accrued prior to the date this Agreement terminates. Subject to the foregoing, each of Universal or Adaptimmune obligations under Section 1 (to the extent necessary for interpretation of other surviving Sections), Sections 2.6, 2.7, 4.1, 4.2, 7, 8, 11, 12, 13, 14, 15. 17, 18, 19, 20, 21 - 29 shall survive the termination or expiration of this Agreement.

# 16. Anti-Corruption Laws

- 16.1. Both Parties shall ensure that in connection with its obligations under this Agreement, they shall conduct their activities in a manner that is consistent with the Anti-Corruption Laws. Each Party further undertakes that none of its or its Affiliates' employees, directors or officers shall, directly or indirectly, engage in any activities that violate any Anti-Corruption Law (a) in order to influence official action of any Government Official, or (b) with the intention of or as a condition to inducing any person to carry out a duty or function improperly or to reach a favourable decision on an improper basis, in each case in connection with the activities contemplated under this Agreement.
- 16.2. Universal shall promptly provide Adaptimmune with written notice of (a) becoming aware of a Material Anti-Corruption Law Violation by it or any of its employees, directors or officers with respect to the subject matter of this Agreement, or (b) upon receiving a formal notification that it or any of its employees, directors or officers is the target of a formal investigation by any Governmental Authority for a Material Anti-Corruption Law Violation.
- 16.3. Universal acknowledges that its undertakings given in this Section 16 are material to Adaptimmune in entering into this Agreement. Notwithstanding any other provision of this Agreement, if Adaptimmune becomes aware of what it determines, acting reasonably, to be a breach of these undertakings, then Adaptimmune shall be entitled to terminate this Agreement in its entirety, and any other agreement among the Parties, on notice with immediate effect. Subject to the accrued rights of the Parties pursuant to termination, Adaptimmune shall have no liability to Universal for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination. At the sole discretion of Adaptimmune, any breach of a Universal obligation with respect to its obligation in this Section 16 may be cured (if capable of

being cured) within a reasonable period of time after learning of such material breach or Material Anti-Corruption Law Violation.

### 17. Assignment

17.1. Neither Party may assign its rights or except as otherwise explicitly provided, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that a Party shall always have the right, without such consent: (a) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or licensees; and (b) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or, subject to the terms of Section 15.6 to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates, provided that such Party shall provide written notice to the other Party within ninety (90) days after such assignment or delegation. All validly assigned rights of any of Universal or Adaptimmune shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such party shall be binding on and be enforceable against, the permitted successors and assigns of such party. Any attempted assignment or delegation in violation of this Section 17 shall be void.

# 18. Severability

To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision will be given no effect by any of the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law and if the rights or obligations of any Party will not be materially and adversely affected, all other provisions of this Agreement shall remain in full force and effect, and each Party shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of each of the Parties.

# 19. Governing Law, Jurisdiction, Venue

19.1. <u>Governing Law</u>. This Agreement and any dispute or claim arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by and construed in accordance with the laws of England excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

- 19.2. Arbitration. Save for any dispute relating to ownership of Intellectual Property Rights or validity of any Intellectual Property Rights which shall be dealt with by the appropriate court of competent jurisdiction, any dispute or claim arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination shall be referred to and finally resolved by arbitration under the rules of the International Chamber of Commerce which only are deemed incorporated into this Section 19.2. The place of arbitration shall be London, if the dispute is brought by Universal, and San Francisco, California if the dispute is brought by Adaptimmune. The language to be used in the arbitration procedures shall be English. The arbitration proceedings including any outcome shall be confidential. Nothing in this Section 19.2 will preclude any of the Parties from seeking equitable interim or provisional relief from a court of competent jurisdiction including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such party or to preserve the status quo pending the arbitration proceeding.
- 19.3. <u>Number of Arbitrators</u>. The number of arbitrators shall be three (3) of which Adaptimmune and Universal shall appoint one (1), the arbitrators so appointed will select the third and final arbitrator. The arbitrators shall have experience of pharmaceutical licensing disputes.

## 20. Dispute Resolution

- 20.1. If a dispute arises between the Parties relating to the existence, negotiation, validity, formation, interpretation, breach, performance or application of this Agreement, the Parties shall use the following non-binding procedure in good faith prior to any Party pursuing judicial remedies provided that this shall not prevent any Party pursuing interim remedies to protect their rights.
- 20.2. Each Party shall notify the other Party of the dispute in accordance with this Section 20. The Parties shall use good faith efforts to resolve such dispute within thirty (30) days after delivery of such notice, which good faith efforts shall include at least one in-person meeting between representatives of each Party having decision-making authority. For Universal, the representatives shall be the President or his or her designee. For Adaptimmune the representative shall be the Chief Executive Officer. All discussions under this Section 20 are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.
- 20.3. If Universal or Adaptimmune are unable to resolve the dispute in accordance with this Section 20, any Party may initiate arbitration in accordance with Section 19.

### 21. Notices

21.1. <u>Notice Requirements</u>. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or electronic mail, or by internationally recognised overnight delivery service that maintains records of delivery,

addressed to the Parties at their respective addresses specified in Section 21.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 21. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or electronic mail, or on the second Business Day (at the place of delivery) after deposit with an internationally recognised overnight delivery service. Any notice delivered by facsimile or electronic mail shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 21 is not intended to govern the day-to-day business communications necessary between any parties in performing their obligations under the terms of this Agreement.

### 21.2. Address for Notice.

For: Universal

Address: Attn: [\*\*\*], President

Universal Cells 3005 1st Avenue Seattle, WA 98121

Email: [\*\*\*]@universalcells.com

For: Adaptimmune Address: as for registered office

Facsimile: N/A

For the attention of: COO and General Counsel

### 22. Relationship of the Parties

The status of any party under this Agreement shall be that of an independent contractor. Nothing contained in this Agreement shall be construed as creating a partnership, joint venture or agency relationship between any of the parties or, except as otherwise expressly provided in this Agreement, as granting any Party the authority to bind or contract any obligation in the name of or on the account of another party or to make any statements, representations, warranties or commitments on behalf of another Party. All persons employed by a Party shall be employees of such Party and not of another Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such party.

# 23. Entire Agreement

This Agreement together with the Sublicenses constitutes the entire agreement between the Parties with respect to the subject matter of the Agreement. This Agreement together with the Sublicenses supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement. Each Party confirms that it is not relying on any statements, representations, misrepresentation, warranties or covenants of any person (whether a party to this Agreement or not) except as specifically set out in this Agreement or in the Sublicenses. Nothing in this Agreement is intended to limit or exclude any liability for fraud. All Schedules referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any

inconsistency between any such Schedules and this Agreement, the terms of this Agreement shall govern save that in relation to any licence to the Sublicensed IP, to the extent there is any conflict between the provisions of this Agreement and the terms of such Sublicenses, the terms of the Sublicenses shall prevail.

### 24. English Language

This Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

#### 25. Amendment

Any amendment or modification of this Agreement must be in writing and signed by authorised representatives of each Party.

#### 26. Waiver and Non-Exclusion of Remedies

Any failure of a Party to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by law or otherwise available, except as expressly set forth herein.

### 27. Further Assurance

Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that any other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

# 28. Expenses

Except as otherwise expressly provided in this Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such party incidental to the negotiation, preparation, execution and delivery of this Agreement.

# 29. Counterparts

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile

transmission or by electronic mail in "portable document format" (".pdf") shall be as effective as an original executed signature page.

THIS AGREEMENT IS EXECUTED by the authorised representatives of the parties as of the date first written above.

SIGNED for and on behalf of UNIVERSAL CELLS, INC.

/s/ Noboru Yamaji

Signature

Name: Noboru Yamaji Title: President SIGNED for and on behalf of ADAPTIMMUNE LIMITED

/s/ Helen Tayton-Martin

Signature

Name: Helen Tayton-Martin Title: Chief Business Officer

# 

THIS PAGE AND THE FOLLOWING 6 PAGES OF THIS SCHEDULE HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

[\*\*\*]

AGREEMENT
BETWEEN:
ADAPTIMMUNE LIMITED (1)
and
UNIVERSAL CELLS, INC. (2)
HLA/AAV Sub-Licence

This **HLA/AAV Sublicence AGREEMENT** (the **"Sub-Licence"**) is made as of the 25th day of November 2015 (the **"Effective Date"**) by and between:

(1) ADAPTIMMUNE LIMITED, a company incorporated in England and Wales with its registered address at 101 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY ("Adaptimmune");

and

**(2) UNIVERSAL CELLS, INC.**, a company incorporated in the State of Washington with principal office at 720 Broadway, Seattle, WA 98122 ("**Universal**").

# **Background**

- (A) WHEREAS Universal has taken a licence from the University of Washington in relation to certain Intellectual Property Rights for Gene Editing Technology, HLA Engineering Technology and a cell line (defined further below) and has certain related know-how (defined below as the AAV/HLA-Engineering Licence);
- (B) WHEREAS Universal and Adaptimmune have entered into a Research and Collaboration Licence Agreement on or about the Effective Date which provides for entry into a sub-licence under the AAV/HLA-Engineering Licence; and
- (C) WHEREAS the parties have agreed to a sublicence under the AAV/HLA-Engineering Licence on the terms and conditions set out below.

### Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Universal and Adaptimmune intending to be legally bound, agree as follows:

### 1. Definitions.

For purposes of interpreting this Agreement, the following terms have the following meanings ascribed to them:

- 1.1. "Confidential Information" means any information or materials (biological, chemical, or otherwise) disclosed by University and not generally known to the public, including any information comprised of those materials, and including without limitation the inventions covered by the Licensed Patents and in each case provided under the AAV/HLA-Engineering Licence. Confidential Information does not include any information that:
  - 1.1.1. is or becomes part of the public domain through no fault of receiving Party;
  - 1.1.2. is known to receiving Party prior to the disclosure by the disclosing Party, as evidenced by documentation;
  - 1.1.3. is publicly released as authorized under this Agreement by University, its employees or agents;
  - 1.1.4. is subsequently obtained by a Party from a Third Party who is authorized to have such information; or
  - 1.1.5. is independently developed by a Party without reliance on any portion of the Confidential Information received from the disclosing Party and without any breach of this Agreement as evidenced by documentation.
- 1.2. "Event of Force Majeure" means an unforeseeable act that wholly prevents a Party from performing one or more of its material duties under this Agreement and that is outside of the reasonable control of the Party. An Event of Force Majeure includes acts of war or of Nature, insurrection and riot, and labor strikes. An Event of Force Majeure does not mean a Party's inability to obtain a Third Party's consent to any act or omission.
- 1.3. "**Group 2 Scope**" means co-exclusive for the construction, sale and use of cell lines derived from Stem Cells using Group 2 Licensed Patents specifically for: i) in vitro discovery and development of pharmaceutical agents; ii) in vitro discovery, development and validation of diagnostic targets; and iii) in vitro development of

engineered cell lines for bioproduction of pharmaceutical agents; exclusive for the development and use of therapeutic products where the construction or manufacture of the therapeutic product itself utilized Group 2 Licensed Patents and in each case within the Fields of Use.

- 1.4. "AAV/HLA-engineering Licence" means the Licence and Material Transfer Agreement between Universal and the University dated 27 June 2014 and attached as Schedule 5;
- 1.5. "**Product Family 1**" means Licensed Products that are vectors or cell lines for research and development purposes. "**Product Family 2**" means Licensed Products in a therapeutic.
- 1.6. "Fields of Use" means immunotherapy and wherein the administered product or therapy incorporates a form of T-cells including, but without limitation, genetically engineered T-cells or stem cell derived T-cells.
- 1.7. **"Licensed Materials**" means the materials provided by Universal to Company, which were originally provided by University under the AAV/HLA-engineering licence (including those listed in Exhibit B), and includes any Licensed Materials contained within materials derived by Adaptimmune or Universal under the Research and Collaboration Agreement from such Licensed Materials.
- 1.8. "Licensed Patents" means the patents and patent applications (including all provisional, nonprovisional, and PCT patent applications, and all national stage and foreign equivalents of the foregoing, accordingly) listed in Section A1 "Licensed Patents" of attached Exhibit A "Patent License Schedule", all divisionals and continuations of these patent applications, all patents issuing from these applications, divisionals, and continuations and any reissues, reexaminations and extensions of these patents including any foreign equivalents of such listed patent applications and patents or patent applications claiming priority from such listed patent applications. Claims in continuations-in-part applications are included in Licensed Patents only to the extent such claims are supported by a patent or patent application set forth in Section A1 "Licensed Patents" of Exhibit A "Patent License Schedule" to benefit from the priority date of such patent or patent application and to the extent such claims are not encumbered by Third Party rights.
  - 1.9. "Licensed Product" means "Products" as defined under the Research and Collaboration Agreement.
- 1.10. "Research and Collaboration Agreement" means the agreement between the parties of date on or around the Effective Date and entitled "RESEARCH COLLABORATION AND LICENCE AGREEMENT RELATING TO GENE EDITING AND HLA-ENGINEERING TECHNOLOGY"
  - 1.11. "Territory" means worldwide.
  - 1.12. "Third Party" means an individual or entity other than Adaptimmune and Universal.

1.13. "Valid Claim" means (i) a claim in an issued and unexpired patent included in the Licensed Patents that: (a) has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and not subject to appeal, (b) has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, (c) has not been lost through an interference, re-examination, or reissue proceeding; or (ii) a pending claim of a pending patent application included in the Licensed Patents.

### 2. Term.

The term of this Sub-licence will commence on the Effective Date and, unless terminated earlier as provided in Article 8 "Termination", will expire on the date on which no Valid Claim in a Licensed Patent is pending or subsisting in any country in the Territory.

### 3. Grant of License.

# 3.1. Adaptimmune's Rights.

- 3.1.1. <u>License Grant for Group 1 Licensed Patents</u>. Subject to the terms and conditions of this Agreement, Universal hereby grants to Adaptimmune, and Adaptimmune hereby accepts, a non-exclusive sub-license under Universal's rights in Group 1 Licensed Patents to make, have made on Adaptimmune's behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products in the Territory in the Field of Use.
- 3.1.2. <u>License Grant for Group 2 Licensed Patents</u>. Subject to the terms and conditions of this Agreement, Universal hereby grants to Adaptimmune, and Adaptimmune hereby accepts, a sub-license with scope restricted co-exclusivity and scope restricted exclusivity as defined in Group 2 Scope, under Universal's rights in Group 2 Licensed Patents to make, have made on Adaptimmune's behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products in the Territory in the Field of Use. Universal will not grant to any Third Party any sub-license under the Group 2 Licensed Patents for the use, offering to sell, sale, disposal or making of any products within the Field of Use.
- 3.1.3. <u>License Grant for Group 3 Licensed Patents</u>. Subject to the terms and conditions of this Agreement, Universal hereby grants to Adaptimmune, and Adaptimmune hereby accepts, an exclusive sub-license under Universal's rights in Group 3 Licensed Patents to make, have made on Adaptimmune's behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products in the

Territory in the Field of Use. Universal will not grant to any Third Party any sub-license under the Group 3 Licensed Patents for the use, offering to sell, sale, disposal or making of any products within the Field of Use.

- 3.1.4. <u>License Grant for Licensed Materials</u>. Subject to the terms and conditions of this Agreement, Universal hereby grants to Adaptimmune, and Adaptimmune hereby accepts, a non-exclusive sub-license under Universal's rights in Licensed Materials to use the Licensed Materials in research and development activities related to the Licensed Products, and in the creation of Licensed Products. For avoidance of doubt, Adaptimmune is not granted the right to use Licensed Materials other than in the development of Licensed Product, or in the construction or manufacture of Licensed Product.
- 3.1.5. <u>Sublicenses</u>. Adaptimmune may sublicense its rights under this Sublicense to its Affiliates without any need for prior consent from Universal and provided that such Affiliates agree to substantially the same terms as contained in this Sub-licence and Adaptimmune remains responsible for the compliance and performance of such Affiliates with the terms of this Sub-licence.
- 3.1.6. <u>Provision of Agreement to University</u>. Adaptimmune agrees that a copy of this Agreement may be provided to the University as required by the terms of the AAV/HLA-engineering licence. Universal will use reasonable efforts to ensure that the University keeps the terms of this Agreement confidential.
- 3.1.7. The license granted in this Agreement is limited to the inventions that are expressly claimed in the Licensed Patents. No provision of this Agreement grants Adaptimmune, by implication, estoppel or otherwise, any rights other than the rights expressly granted it in this Agreement to the Licensed Patents, Licensed Materials, or to any other University-owned technology, materials, patent applications, or patents.
- 3.2. The United States Government's Rights. The inventions covered in the Licensed Patents arose, in whole or in part, from federally supported research and the federal government of the United States of America has certain rights in and to the Licensed Patents as those rights are described in Chapter 18, Title 35 of the United States Code and accounting regulations, including Part 401, Chapter 37 of the Code of Federal Regulation. The Parties' rights and obligations under this Agreement to any government-funded inventions, including the grant of sub-license set forth in Subsection 3.1.1, are subject to the applicable terms of the aforementioned United States laws.

3.3. <u>University's Reservation of Rights</u>. To the extent required by the University under the AAV/HLA-engineering Licence, Universal retains for itself an irrevocable, nonexclusive license to make, have made, and use products, processes, and other subject matter covered by the Licensed Patents or Licensed Materials in the Field of Use for academic research, medical, instructional, or any other academic purpose. Expressly included within this University reservation of rights is the right (i) to use the Licensed Patents in sponsored research or collaborative research with any Third Party but only to the extent no such Third Party is granted any rights to the Licensed Patents or to commercialize Licensed Products, (ii) to grant material transfer agreements to materials whose composition of matter is covered by the Licensed Patents where the use of such materials is restricted to academic research, medical, instructional, or any other academic purpose, and (iii) to publish any information included in the Licensed Patents or any other information that may result from University's research. Universal will use reasonable efforts to (a) within a reasonable period of time after the Effective Date, request from the University prior notice of any sponsored research or collaborative research with any commercial Third Party and obtain University's agreement to such provision; (b) ensure that any publication (to the extent University provides notice of such publication to Universal) does not impact on the ability of the University to obtain patent protection in relation to any of the Licensed Patents.

# 3.4. Mandatory Sublicensing.

- 3.4.1. Under the AAV/HLA-engineering licence, the University has the right to request mandatory sublicensing in certain fields. Universal will use reasonable efforts to obtain from the University as soon as reasonably possible after the Effective Date a written confirmation that such mandatory sublicensing shall not apply in relation to mandatory sublicensing in the Fields of Use during the term of the Research and Collaboration Agreement provided Adaptimmune is complying with the terms of the Research and Collaboration Agreement.
- 3.4.2. If Universal receives notice under the AAV/HLA-engineering licence that the University has been solicited by a Third Party who wishes to license Licensed Patents for any field within the Field of Use that Adaptimmune or Universal is not diligently pursuing (hereinafter "Third Party Field"), Universal shall so notify Adaptimmune, and Adaptimmune shall be entitled to be actively involved in any notifications made to University in relation to such Third Party Field notification from University. Universal and Adaptimmune shall discuss which of the following options should be exercised in response to such University's notification:

- 3.4.2.1. <u>Development Plan.</u> Provide University with a reasonable rationale as to why offering a sublicense in Third Party Field would be competitive with market opportunity Adaptimmune or Universal is either actively pursuing, or planning on pursuing; or
- 3.4.2.2. <u>Direct Grant.</u> Universal to grant a sublicense to the said soliciting Third Party in the Third Party Field on commercially reasonable licence terms, such terms being subject to review and approval by Adaptimmune. Adaptimmune will not unreasonably withhold or delay its review and approval of such terms, but will be involved in discussions relating to the scope of any sublicense granted and the terms applicable to such grant.
- 3.4.3. <u>University Direct Grant.</u> Adaptimmune understands that if Universal has not proceeded under either Subsection 3.4.2.1 or 3.4.2.2 within ninety (90) days of notification to Universal by University under AAV/HLA-engineering licence, University may directly grant a license to such Third Party in the Third Party Field for the benefit of University exclusive of any benefit to Adaptimmune. Universal and Adaptimmune will work together to ensure that one of the options under 3.4.2.1 or 3.4.2.2 is taken within the ninety (90) day period.

# 4. Applications and Patents.

- 4.1. Patent Application Filings during the Term of this Agreement.
- 4.1.1. <u>University Prosecutes Patents</u>. Adaptimmune understands that the University retains the sole and exclusive right to file or otherwise prosecute Licensed Patents. Universal shall use reasonable efforts to copy Adaptimmune on any material correspondence, material filings or other material communications relating to the prosecution of the Licensed Patents to the extent relevant to the Fields of Use and in each case (a) which relate to the filing or not filing of any patent application or patent, the lapse of any patent or patent application, in which the scope of any claims are restricted or narrowed, any third party observations or oppositions or any communication where any patent office indicates any claim is invalid or insufficient for any reason and any response to such patent office communication; and (b) to the extent possible under the AAV/HLA-engineering Licence will provide Adaptimmune with an opportunity to comment on any proposed response, including the countries in which any patent application or patent is filed.
- 4.1.2. <u>University's Independent Patent Filings</u>. Universal shall immediately notify Adaptimmune where University wishes to file, prosecute or maintain any Licensed Patents in a country that Universal does not wish the University to file in.

- 4.2. <u>Maintenance of Licensed Patents</u>. Universal shall notify Adaptimmune on a timely basis of any failure on its part to comply with any reimbursement or other payment obligation under the AAV/HLA-engineering licence or other default which may cause or result in any Licensed Patent to cease to fall within the Sub-licence or which might result in any Licensed Patent lapsing or ceasing to be filed, prosecuted or maintained. Such notice shall where possible be provided in sufficient time for Adaptimmune to correct any non-payment or reimbursement obligation of Universal. Any correction made by Adaptimmune shall be reimbursed in full by Universal.
- 4.3. <u>Ownership of the Licensed Patents</u>. No provision of this Agreement grants Adaptimmune any rights, titles, or interests (except for the grant of license in Subsection 3.1.1 "License Grant" of this Agreement) in the Licensed Patents.

### 5. Commercialization.

- 5.1. <u>Covenants Regarding the Manufacture of Licensed Products</u>. Adaptimmune hereby covenants and agrees that the manufacture, use, sale, or transfer of Licensed Products will comply with all applicable federal and state laws, including all federal export laws and regulations. Adaptimmune understands that there is a requirement under the AAV/HLA-engineering licence requiring that all products embodying or produced through the use of an invention that is subject to the rights of the federal government of the United States of America shall be substantially manufactured in the United States of America. Due to the nature of the product concerned, Universal understand that this may not always be commercially feasible and hence Universal agrees to work with Adaptimmune and to approach the University on a timely basis during the performance of the Research Plan (as defined in the Research and Collaboration Agreement) to obtain waiver from the University in relation to such manufacture and as permitted in accordance with 35 United States Code Section 204.
- 5.2. <u>Use of University's Name and Trademarks or the Names of University Faculty, Staff, or Students</u>. No provision of this Agreement grants Adaptimmune or any of its Sublicensees any right or license to use the name or trademarks of University or the names or identities of any member of the faculty, staff, or student body of University. Adaptimmune shall not use, and shall not permit a Sublicensee to use, any such trademarks, names, or identities without University's and, as the case may be, such member's prior written approval.

### 5.3. Records Retention and Audit Rights.

- 5.3.1. <u>Records Retained</u>. Throughout the term of this Agreement and for 5 years thereafter, Adaptimmune, at its expense, shall keep and maintain and shall cause each Sublicensee to keep and maintain complete and accurate records of all sales, leases, and other dispositions of Licensed Products during the term of this Agreement and all other records related to this Agreement.
- 5.3.2. <u>Auditing Rights</u>. Adaptimmune shall permit, at the request of University, one or more accountants selected exclusively by the University ("Accountants") to have access to Adaptimmune's records and books of account pertaining to this Agreement, but not more than once per calendar year. Accountants' access will be during ordinary working hours to audit Adaptimmune's records for any payment period ending prior to such request, the correctness of any report or payment made by Universal under this Agreement, or to obtain information as to the payments due for any period in the case of failure of Adaptimmune to report pursuant to the terms of this Agreement. Any such inspection shall be subject to Accountants signing confidentiality agreements with Adaptimmune to ensure the confidentiality of Adaptimmune's information. Access under this clause shall only be provided to records relating to sales of Licensed Products and not to any other products or services. The cost of any audit under this clause shall be at the cost of the University.
- 5.3.3. <u>Scope of Disclosure</u>. Accountants shall not disclose to University any information relating to the business of Adaptimmune except that which is necessary to inform University of: the accuracy or inaccuracy of Adaptimmune's reports provided to Universal under this Agreement (and which Universal subsequently provides to University under the AAV/HLA-engineering licence); and the extent of any inaccuracy or noncompliance.

# 6. Infringement.

- 6.1. Third-Party Infringement of a Licensed Patent.
- 6.1.1. <u>Notice of Third Party's Infringement</u>. If a Party learns of substantial, credible evidence that a Third Party is infringing a Licensed Patent in the Field of Use in the Territory, that Party will promptly deliver written notice of the possible infringement to the other Party, describing in detail all relevant information to which that

Party has access or control suggesting infringement of the Licensed Patent. Adaptimmune understands that under the terms of the AAV/HLA-engineering licence, Universal is not able to grant a right to Adaptimmune to enforce the Licensed Patents. Universal will work with Adaptimmune in relation to the exercise of Universal's rights to enforce and prosecute an infringement or potential infringement action under the AAV/HLA-engineering licence and to the extent permitted by the University, will permit Adaptimmune to be present at any court hearings, material meeting or other actions taken in relation to enforcement of the Licensed Patents to the extent in each case relevant to the Fields of Use or scope of Research and Collaboration Agreement. To the extent Universal proposes to settle any action for infringement or potential infringement, Universal will discuss and obtain Adaptimmune's approval to such settlement, such approval not to be unreasonably withheld or delayed. To the extent the University has control of any infringement suit or action under the AAV/HLA-engineering licence, Universal will to the extent permitted by University keep Adaptimmune informed of the progress of such infringement suit or action and permit Adaptimmune to be actively involved in such infringement suit or action including the terms of any sublicense proposed to be granted by the University. Any involvement of Adaptimmune shall be at Adaptimmune's cost and expense save where University requests any assistance from Adaptimmune, in which case University shall pay for any direct associated expenses related to provision of such assistance.

# 7. Patent Validity.

- 7.1. Notice and Investigation of Third Party Challenges. If any Third Party challenges the validity or enforceability of any of the Licensed Patents, the Party having such information shall immediately notify the other Party. Universal shall keep Adaptimmune informed of the status of any defense of any claim challenging validity or enforceability, where the University assumes control and defense of the claim in accordance with the terms of the AAV/HLA-engineering licence. Where Universal assumes the defense of any such claim, Universal will cooperate with Adaptimmune and enable Adaptimmune to be actively involved in the defense of such claim and any decisions taken in relation to such claim at Adaptimmune's cost and expense.
- 7.2. <u>Enforceability of Licensed Patents</u>. Notwithstanding challenge by any Third Party, any Licensed Patent will be enforceable under this Agreement until such Licensed Patent is determined to be invalid.

#### 8. Termination.

### 8.1. By Universal.

- 8.1.1. <u>Breach by Adaptimmune</u>. If Adaptimmune breaches or fails to perform one or more of its material duties under this Agreement, Universal may deliver to Adaptimmune a written notice of default. Universal may terminate this Agreement by delivering to Adaptimmune a written notice of termination if the default has not cured in full within 60 days of the delivery to Adaptimmune of the notice of default.
- 8.1.2. Events of Default. Universal may terminate this Agreement by delivering to Adaptimmune a written notice of termination at least 10 days prior to the date of termination if Adaptimmune (i) becomes insolvent; (ii) voluntarily files or has filed against it a petition under applicable bankruptcy or insolvency laws that Adaptimmune fails to have released within 30 days after filing; (iii) proposes any dissolution, composition, or financial reorganization with creditors or if a receiver, trustee, custodian, or similar agent is appointed; (iv) makes a general assignment for the benefit of creditors; or (v) if Adaptimmune challenges the validity of the Licensed Patents.
- 8.2. <u>By Adaptimmune</u>. Adaptimmune may terminate this Agreement at any time by delivering to University a written notice of termination at least 60 days prior to the effective date of termination.
- 8.3. Automatic termination. This Agreement shall automatically terminate on termination of the Research and Collaboration Agreement.

# 8.4. Effect of Termination.

- 8.4.1. <u>License Terminated</u>. After termination of this Agreement, Adaptimmune shall destroy Licensed Materials, and Adaptimmune shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products.
- 8.5. <u>Right to continue licence on termination of AAV/HLA-engineering licence</u>. Universal shall notify Adaptimmune immediately if it receives any notice of termination of the AAV/HLA-engineering licence and of any actual termination of the AAV/HLA-engineering licence. At any time within 30 days following termination of the AAV/HLA-engineering licence, Adaptimmune may notify University and Universal that it wishes to enter into a direct license with University in order to retain its rights to the Licensed Patents and/or Licensed Materials granted to it under its Sublicense (such 30-day period following termination, the "Initial Notice Period"). Following receipt

of such notice, Universal shall procure (to the extent necessary under the AAV/HLA-engineering licence) that University and Adaptimmune shall enter into a license agreement the terms of which shall be substantially similar to the terms of the AAV/HLA-engineering licence; and the scope of such direct license, the licensed territory or the duration of the license grant shall be comparable to the corresponding terms granted under this Agreement; provided that Adaptimmune will be granted at least the same scope of rights as it obtained from Adaptimmune under this Agreement. For the sake of clarity, the financial terms, including without limitation, the running royalty rate and milestone payments, shall be identical to the corresponding financial terms set forth in the AAV/HLA-engineering licence. Notwithstanding the foregoing, Adaptimmune understands that its right to enter into such direct license shall be conditioned upon:

- 8.5.1. <u>Written Notification to University</u>. Adaptimmune informing University in writing, pursuant to Article 21 "Notices" of the AAV/HLA-engineering licence, that it wishes to enter into such direct license with University, within the Initial Notice Period;
- 8.5.2. <u>Good Standing</u>. Adaptimmune being in good standing with Universal under this Agreement, and this Agreement not being the subject of a dispute between Universal and Adaptimmune, or between Universal and University under the AAV/HLA-engineering licence;
- 8.5.3. <u>Valid Sublicense</u>. This Agreement having been validly entered into by Adaptimmune and Sublicensee pursuant to the terms of Section 3.1.5 "Sublicenses" of the AAV/HLA-engineering licence;
- 8.5.4. <u>Sublicensee Certification that Conditions Satisfied</u>. Adaptimmune using reasonable efforts to certify or otherwise demonstrate that the conditions set forth in this Section 8.5 have been met within 30 days of expiration of the Initial Notice Period (or within such longer period of time as University agrees is reasonable under the circumstances, based on the nature and extent of any documentation reasonably requested by University); and
- 8.5.5. <u>Time Limitations</u>. Such negotiations for a direct license not exceeding 90 days from the end of the 30-day (or longer, if applicable) period described in subsection 8.5.4 "Sublicensee Certification that Conditions Satisfied" (subject to extension of said 90-day period by mutual written agreement of University and Sublicensee).

University may, at its sole discretion, waive any of the above requirements. Adaptimmune understands and Universal confirms that if all of the conditions set forth in this Section 8.5 are met, then Adaptimmune will be granted such direct license by University. If any condition set forth in this Section 8.5 is not met, then after

expiration of any time period granted to Adaptimmune with respect to meeting such condition, Adaptimmune shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products and University shall be free to license or not license Licensed Patents to Adaptimmune according to its sole discretion.

### 9. Release, Indemnification, and Insurance.

- 9.1. <u>Adaptimmune's Release</u>. For itself and its employees, Adaptimmune hereby releases University and its regents, employees, and agents forever from any suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of (i) the manufacture, use, lease, sale, or other disposition of a Licensed Product or Licensed Material; or (ii) the assigning or sublicensing of Adaptimmune's rights under this Agreement.
- 9.2. <u>Adaptimmune's Indemnification</u>. Throughout the term of this Agreement and thereafter, Adaptimmune shall indemnify, defend, and hold University and its regents, employees, and agents harmless from all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), relating to or arising out of the manufacture, use, lease, sale, or other disposition of a Licensed Product or Licensed Materials, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to a Licensed Product or Licensed Materials and claims brought by a sublicensee of Adaptimmune.
- 9.3. <u>Universal's Indemnification</u>. Throughout the term of this Agreement and thereafter, Universal shall indemnify, defend and hold Adaptimmune and its employees and agents harmless from all suits, actions, claims, liabilities, demands, damages, losses or expenses (including reasonable attorneys' and investigative expenses), relating to or arising out of any breach by Universal (or any of its agents or employees) of the terms of the AAV/HLA-engineering licence. Such indemnification shall not cover any suits, actions, claims, liabilities, demands, damages, losses or expenses to the extent arising as a result of Adaptimmune's breach of the terms of this Agreement or failure to comply with Section 8.5 above.

# 9.4. Adaptimmune's Insurance.

- 9.4.1. <u>General Insurance Requirement</u>. Throughout the term of this Agreement, or during such period as the Parties shall agree in writing, Adaptimmune shall maintain in full force and effect commercial general liability (CGL) insurance, with single claim limits consistent with industry standards. Such insurance policy will include coverage for claims arising under Section 9.2 above.
- 9.4.2. <u>Clinical Trial Liability Insurance</u>. Within thirty (30) days prior to the initiation of human clinical trials with respect to Licensed Product(s), Adaptimmune shall provide to Universal copies of certificates evidencing the existence and amount of clinical trials liability insurance following request from Universal for copies of such certificates.

# 10. Warranties.

- 10.1. <u>Authority</u>. Each Party represents and warrants to the other Party that it has full corporate power and authority to execute, deliver, and perform this Agreement, and that no other corporate proceedings by such Party are necessary to authorize the Party's execution or delivery of this Agreement.
  - 11.2 Universal Representation and Warranty. Universal represents and warrants that:
    - 11.2.1 it has sufficient rights, title and interests of the Licensed Patents and Licensed Materials to grant the licenses to Adaptimmune as purported to be granted pursuant to this Agreement;
    - 11.2.2 as at the Effective Date it is not in breach of any of the terms of the AAV/HLA-engineering Licence including any failure to perform or cause to happen or be performed any performance milestones specified in the AAV/HLA-engineering Licence.

- 10.2.1. General Disclaimers. EXCEPT FOR THE EXPRESS WARRANTY SET FORTH IN SECTION 11.1 "Authority" OF THIS AGREEMENT, UNIVERSAL AND ADAPTIMMUNE DISCLAIM AND EXCLUDE ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH LICENSED PATENT AND EACH LICENSED PRODUCT, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.
- 10.2.2. <u>Patent Disclaimers</u>. Adaptimmune understands that the University expressly disclaims any warranties concerning and makes no representations:
  - 10.2.2.1. Patent Issuance. That the Licensed Patent(s) will be approved or will issue;
  - 10.2.2.2. Licensed Patent Validity/Scope. Concerning the validity or scope of any Licensed Patent; or
  - 10.2.2.3. <u>Non-Infringement</u>. That the manufacture, use, sale, lease or other disposition of a Licensed Product or Licensed Material will not infringe a Third Party's patent or violate a Third Party's intellectual property rights.

# 11. Damages.

- 11.1. Remedy Limitation. EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, IN NO EVENT SHALL UNIVERITY BE LIABLE FOR (A) PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT AND (B) AND IN NO EVENT SHALL EITHER PARTY OR THE UNIVERSITY BE LIABLE FOR LOST PROFITS (OTHER THAN IN THE CASE OF THE PARTIES DIRECT LOSS OF PROFITS ARISING AS A RESULT OF A BREACH OF CONFIDENTIALITY), LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OF ANY KIND.
- 11.2. <u>Damage Cap.</u> IN NO EVENT WILL UNIVERSITY'S TOTAL LIABILITY FOR THE BREACH OR NONPERFORMANCE OF THIS AGREEMENT EXCEED THE AMOUNT OF PAYMENTS PAID TO UNIVERSITY BY UNIVERSAL UNDER THE AAV/HLA-ENGINEERING LICENCE. THIS LIMITATION WILL APPLY TO CONTRACT, TORT, AND ANY OTHER CLAIM OF WHATEVER NATURE.

# 12. Amendment and Waiver.

This Agreement may be amended from time to time only by a written instrument signed by the Parties. No term or provision of this Agreement will be waived and no breach excused unless such waiver or consent will be in writing and signed by the Party claimed to have waived or consented. No waiver of a breach will be deemed to be a waiver of a different or subsequent breach.

# 13. Assignment.

The rights and licenses granted by Universal in this Agreement are personal to Adaptimmune and Adaptimmune shall not assign its interest or delegate its duties under this Agreement without the written consent of Universal; any such assignment or delegation made without written consent of Universal will not release Adaptimmune from its obligations under this Agreement. The preceding sentence notwithstanding, Adaptimmune, without the prior approval of Universal, may assign all, but no less than all, its rights and delegate all, but no less than all, its duties under this Agreement to a Third Party provided that:

- (i) the assignment is made to such Third Party as a part of and in connection with (a) the sale by Adaptimmune of all but no less than all of its assets to the Third Party, (b) the sale, transfer, or exchange by the shareholders, partners, or equity owners of Adaptimmune of a majority interest in Adaptimmune to the Third Party, or (c) the merger of Adaptimmune into the Third Party (each of the events described in part (a), (b) or (c) of this paragraph, an "Acquisition"),
- (ii) Adaptimmune obtains from such Third Party written agreement to honor all obligations under this Agreement accrued by Adaptimmune before Acquisition and all obligations under this Agreement to accrue by such Third Party assignee after Acquisition, including any and all financial obligations, and
- (iii) no later than 10 days after the close of the transaction pursuant to which such Acquisition is made, Adaptimmune shall provide written notice to Universal of the Acquisition, as well as a substitution of parties document, in which such Third Party assignee assumes responsibility for all of Adaptimmune's outstanding and future obligations relating to this Agreement. Any assignment made in violation of this Article will be void and will, without further act, cause the immediate termination of this Agreement, effective retroactively to the date of the Acquisition.

This Agreement will inure to the benefit of Adaptimmune and Universal and their respective permitted assignees and trustees.

# 14. Confidentiality.

14.1. <u>Form of transfer.</u> Confidential Information may be conveyed in tangible or intangible form. Disclosing Party must clearly mark its Confidential Information "confidential." If disclosing Party communicates Confidential

Information in non-written form, it shall reduce such communications to writing, clearly mark it "confidential", and provide a copy to receiving Party within 30 days of original communication at the address in Article 21 "Notices".

- 14.2. No Unauthorized Disclosure of Confidential Information. Beginning on the Effective Date and continuing throughout the term of this Agreement and thereafter for a period of 5 years, receiving Party shall not disclose or otherwise make known or available to any Third Party any disclosing Party Confidential Information, without the express prior written consent of disclosing Party. Notwithstanding the foregoing, receiving Party shall be permitted to disclose disclosing Party Confidential Information to (i) actual or potential investors, lenders, consultants, collaborators, sublicensees, or development partners, which disclosure will be made under conditions of confidentiality and limited use and (ii) its attorney or agent as reasonably required. In no event shall receiving Party incorporate or otherwise use disclosing Party's Confidential Information in connection with any patent application filed by or on behalf of receiving Party. Receiving Party shall restrict the use of disclosing Party's Confidential Information exclusively to the terms of this Agreement. Receiving Party shall use reasonable procedures to safeguard disclosing Party's Confidential Information.
- 14.3. Access to University Information. University is an agency of the state of Washington and is subject to the Washington Public Records Act, RCW 42.56 et seq., ("Act"). If University receives a request for public records under the Act for documents containing Adaptimmune Confidential Information, and if University concludes that the documents are not otherwise exempt from public disclosure, University will provide Universal notice of the request before releasing such documents. Universal will provide such notice to Adaptimmune. Such notice will be provided in a timely manner to afford Adaptimmune sufficient time to review such documents and/or seek a protective order to the extent agreed as necessary with Universal in good faith and utilizing the procedures described in RCW 42.56.540
- 14.4. <u>Disclosure as Required by Law</u>. Either Party shall have the right to disclose the other Party's Confidential Information as required by law or valid court order, provided that such Party shall inform the Party who owns such Confidential Information prior to such disclosure and shall limit the scope and recipient of disclosure to the extent required by such law or court order.

# 15. Consent and Approvals.

Except as otherwise expressly provided, all consents or approvals required under the terms of this Agreement must be in writing and will not be unreasonably withheld or delayed.

# 16. Construction.

The headings preceding and labeling the sections of this Agreement are for the purpose of identification only and will not in any event be employed or used for the purpose of construction or interpretation of any portion of this Agreement. As used herein and where necessary, the singular includes the plural and vice versa, and masculine, feminine, and neuter expressions are interchangeable.

# 17. Enforceability.

If a court of competent jurisdiction adjudges a provision of this Agreement unenforceable, invalid, or void, such determination will not impair the enforceability of any of the remaining provisions hereof and the provisions will remain in full force and effect.

# 18. No Third-Party Beneficiaries.

No provision of this Agreement, express or implied, confers upon any person other than the Parties to this Agreement and the University any rights, remedies, obligations, or liabilities hereunder.

# 19. Language.

Unless otherwise expressly provided in this Agreement, all notices, reports, and other documents and instruments that a Party hereto elects or is required by the terms of this Agreement to deliver to the other Party hereto will be in English.

# 20. Notices.

All notices, requests, and other communications that a Party is required or elects to deliver will be in writing and will be delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other Party at its address set forth below or to another address as a Party may designate by notice given pursuant to this article:

If to Universal: Universal Cells, Inc

Attn: Claudia Mitchell, CEO

720 Broadway Seattle, WA 98122 Email: [\*\*\*]

If to Adaptimmune: Adaptimmune Limited

Attn: Helen Tayton-Martin, COO 101 Park Drive, Milton Park, Abingdon

# Oxfordshire, OX14 4RY E-mail: [\*\*\*] with a copy to legal@adaptimmune.com

# 21. Patent Marking.

Adaptimmune shall mark all material forms of Licensed Product(s) or packaging pertaining thereto made and sold by Adaptimmune in the United States with patent marking conforming to 35 U.S.C. §287(a), as amended from time to time. Such marking shall further identify the pendency of any U.S. patent application and/or any issued U.S. or foreign patent forming any part of the Licensed Patents. All Licensed Product(s) shipped to or sold in other countries will be marked in such a manner as to provide notice to potential infringers pursuant to the patent law and practice of the country of manufacture or sale.

# 22. Publicity.

The Parties will cooperate with one another to review and respond to any press release or similar communication proposed by the other Party regarding the non-confidential subject matter of this Agreement. The specific content and timing of such press releases or similar communication is subject to mutual agreement by the Parties, which will not be unreasonably withheld.

# 23. Relationship of Parties.

In entering into, and performing their duties under, this Agreement, the Parties are acting as independent contractors and independent employers. No provision of this Agreement shall create or be construed as creating a partnership, joint venture, or agency relationship between the Parties. No Party shall have the authority to act for or bind the other Party in any respect.

# 24. Survival.

Immediately upon the termination or expiration of this Agreement all Company's rights under this Agreement will terminate; provided, however, Company's obligations that have accrued prior to the effective date of termination or expiration of this Agreement (e.g., the obligation to report and make payments on sales, leases, or dispositions of Licensed Products and to reimburse University for costs) and the obligations specified in Sections 6.1 "Payments" and 6.4 "Sales Reports" will survive. The obligations and rights set forth in Sections 6.5 "Records Retention and Audit Rights" and 9.3 "Effect of Termination" and Articles 10 "Release, Indemnification, and Insurance", 11 "Warranties", 12 "Damages", 15 "Confidentiality", 29 "Applicable Law" and 30 "Forum Selection" will survive the termination or expiration of this Agreement.

# 25. Collection Costs and Attorneys' Fees.

If a Party fails to perform an obligation or otherwise breaches one or more of the terms of this Agreement, the other Party may recover from the non-performing breaching Party all its costs (including actual attorneys' and investigative fees) to enforce the terms of this Agreement.

# 26. Applicable Law.

The internal laws of the state of Washington will govern the validity, construction, and enforceability of this Agreement, without giving effect to the conflict of laws principles thereof.

# 27. Forum Selection.

A suit, claim, or other action to enforce the terms of this Agreement will be brought exclusively in the state and federal courts of King County, Washington.

# 28. Entire Agreement.

This Agreement (including all attachments, exhibits, and amendments) is the final and complete understanding between the Parties concerning licensing the Licensed Patents. This Agreement supersedes any and all prior or contemporaneous negotiations, representations, and agreements, whether written or oral, concerning the Licensed Patents. This Agreement may not be modified in any manner, except by written agreement signed by an authorized representative of both Parties. Nothing in this Section excludes or limits any liability for fraud or fraudulent misrepresentation.

# Exhibit A

# **Patent License Schedule**

# A1. Licensed Patents:

A1.1 Group 1 Licensed Patents: Non-exclusive grant

UW#	IP#	Short Title	Status	Application Number	Filing Date	Grant
41571	41571.01US2	AAV Isolates and AAV Vectors	Issued/Granted	08/873,168	6/11/1997	Non-exclusive

# A1.2 Group 2 Licensed Patents

UW#		Short Title	Status	Application Number	Filing Date	Grant
41754	41754.01US1	Targeted Gene Modification by Parvoviral Vectors	Converted	60/044,789	4/24/1997	Group 2 Licensed Patents Scope
	41754.02WO2	Targeted Gene Modification by Parvoviral Vectors	Nationalized	PCT/US98/07964	4/20/1998	
	41754.03US1	Targeted Gene Modification by Parvoviral Vectors	Converted	60/106,191	10/28/1998	
	41754.04AU2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	72521/98	4/20/1998	
	41754.05CA2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	2,289,277	4/20/1998	
	41754.06EP2	Targeted Gene Modification by Parvoviral Vectors	Validated	98919818.9	4/20/1998	
	41754.10WO2	Targeted Gene Modification by Parvoviral Vectors	Nationalized	PCT/US99/25462	10/27/1999	
	41754.18US4	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	10/423,604	4/24/2003	
	41754.20FR2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.21DE2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.22CH2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.23IE2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.24GB2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.25US5	Targeted Gene Modification by Parvoviral Vectors	Pending	13/114,117	5/24/2011	
	41754.26CA3	Targeted Gene Modification by Parvoviral Vectors	Pending	2,797,661	4/20/1998	
45039	45039.01GB2	Methods for Improving the Efficiency of Gene Targeting	Pending	1301125.9	1/22/2013	Jointly owned with third party
	45039.02WO2	Methods for Improving the Efficiency of Gene Targeting	Pending	PCT/GB2014/050173	1/22/2014	Jointly owned with third party

# A1.3 Group 3 Licensed Patents

UW#	IP#	Short Title	Status	Application Number	Filing Date	Grant
43950	43950.01US1	HLA Homozygous Cells and Methods of Use Thereof	Converted	60/905,966	3/9/2007	Exclusive all fields
	43950.02US2	HLA Homozygous Cells and Methods of Use Thereof	Issued/Granted	12/044,471	3/7/2008	
	43950.03US4	HLA Homozygous Cells	Issued/Granted	13/333,010	12/21/2011	
45038	N/A	[***]	Not Filed Yet	N/A	N/A	
45365	45365.01US1	B2M-deficient human cells	Converted	61/477,474	4/20/2011	Exclusive all fields
	45365.02WO2 45365.03US2	B2M-deficient human cells B2M-deficient human cells	Nationalized Pending	PCT/US2012/034051 14/111,837	4/18/2012 10/15/2013	
	45365.04CA2	B2M-deficient human cells	Pending	2,833,173	4/18/2012	
	45365.05EP2	B2M-deficient human cells	Pending	12720040.0	4/18/2012	
	45365.06JP2	B2M-deficient human cells	Pending	Not available	4/18/2012	
45826	45826.01US1	HLA Class II Deficient Cells	Converted	61/625,314	4/17/2012	Exclusive all fields
	45826.02WO2	HLA Class II Deficient Cells	Pending	PCT/US2013/032058	3/15/2013	
46825	N/A	[***]	Not Filed Yet	N/A	N/A	
46895	N/A	[***]	Not Filed Yet	N/A	N/A	

# Exhibit B

# **Licensed Materials**

# UW Materials to Transfer to Universal Cells Cell lines [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] [\*\*\*] AAV Vector stocks [\*\*\*]

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# NON-EXCLUSIVE SUB-LICENSE AGREEMENT

**THIS AGREEMENT** ("Agreement") is dated and effective as of the date of last signature ("Effective Date"), and is made by and between Universal and Adaptimmune Limited, an English Adaptimmune with principal offices at 101 Park Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RY ("Adaptimmune"), and Universal Cells, a Corporation under the laws of the state of Washington ("Universal") with principal offices at 720 Broadway, Seattle, WA 98122, agree as follows:

# 1. BACKGROUND

- 1.1 Universal has certain rights to Biological Material known as New naive human embryonic stem cell line Elf1 (as defined in Section 2.1), developed in the laboratory of [\*\*\*] and licensed from the University under a Non-Exclusive License Agreement dated 22 October 2014 ("Elf Licence").
- 1.2 Adaptimmune and Universal have entered in to a Research Collaboration and Licence Agreement relating to gene editing and HLA-Engineering on or about the date of this Agreement ("Collaboration Agreement"), under which the parties agreed to enter into this Agreement.
- 1.3 Universal and University have previously entered into an exclusive license agreement with University for inventions and materials related to or useful for Adeno-associated virus (AAV)-mediated gene targeting and HLA engineering, UW Ref # 34243A on June 27, 2014 "AAV/HLA-engineering Licence". Adaptimmune and Universal have also entered into an exclusive sub-licence agreement under the AAV/HLA-engineering Licence on or about the Effective Date ("Exclusive Agreement").

# 2. DEFINITIONS

2.1 "Biological Material"	means New naive human	embryonic stem cell l	ine - Elf1 (with a U	niversity Reference U	W # 45910).

- 2.2 "Internal Research Field of Use" means internal research. Internal Research Field of Use specifically excludes any use which requires regulatory approval, including any in vitro and in vivo diagnostic or therapeutic applications.
- 2.3 "Product Field of Use" means in vivo therapeutics excluding any therapeutic agent for cardiac regeneration and cardiovascular disease.
- 2.4 "Licensed Product" means a Product as defined in the Collaboration Agreement.
- 2.5 "Licensed Territory" means worldwide.
- 2.6 "Modifications" means any derivatives or modifications of Biological Material that, but for the rights granted under Exclusive Agreement, would otherwise infringe a Valid Claim of Groups 2 and 3 Licensed Patents as defined in Exclusive Agreement.
- 2.7 "Service Partner" means a legal entity that is a Third Party with whom Adaptimmune has contracted to provide services within the Internal Research Field of Use and Product Field of Use. For clarity, a legal entity is only a Service Partner for so long as the definition remains true. If such entity terminates its contractual obligation with Adaptimmune, it thereafter is an arm-length Third Party for the purposes of this Agreement.
- 2.8 "Third-Party" means any individual or entity other than Universal and Adaptimmune or their respective affiliates.
- 2.9 "University" means the University of Washington a public institution of higher education and an agency of the State of Washington acting through its administrative offices at UW CoMotion, 4311 Eleventh Avenue NE, Suite 500, Seattle, WA 98105

# 3. GRANT

- 3.1 Universal hereby grants, and Adaptimmune accepts, a nonexclusive license in the (i) Product Field of Use and Licensed Territory to make, use, offer, and sell Licensed Product(s) for Product Family 2 and (ii) make, use, offer, and sell Licensed Products in the Internal Research Field of Use for Product Family 1. Such license does not include the right for Adaptimmune to transfer any Licensed Products to any Third Parties or affiliates for resale other than as incorporated in a therapeutic product. Such licence shall not include any right to Biological Material.
- 3.2 Service Partners of Adaptimmune shall have the right to transfer Modifications to Service Partners working on behalf of Adaptimmune solely for the purpose of carrying out services in direct connection with using the Modifications in the Internal Field of Use and Product Field of Use. Any such transfer of Modifications to such Service Partner shall be under a written agreement between Adaptimmune and such Service Partner

which (a) shall be in writing, (b) shall be subject to, subordinate to, and consistent with, the terms and conditions of this Agreement, (c) shall not adversely affect the rights of University or Universal or limit the obligations of Adaptimmune under this Agreement, (d) shall contain terms substantially similar to those contained in this Agreement, and (e) shall expressly provide that the Service Partner has no rights to use the Modifications for any purpose other than to perform the services in direct connection with the Licensed Field of Use, and that such Service Partner shall not transfer the Modifications to any Third-Party. Adaptimmune will be responsible for the performance of all Service Partner in compliance with all obligations of Adaptimmune under this Agreement.

- 3.3 The term of this Agreement shall commence as of the Effective Date and shall expire on termination of the Collaboration Agreement or at such point as a decision is taken by both parties under the Collaboration Agreement that the Biological Material and any Modifications are no longer required for use under the Collaboration Agreement.
- 3.4 Nothing in this Agreement shall be construed as granting by implication, estoppel, or otherwise any licenses or rights under patents or patent applications of Universal.

# 4. NEGATION OF WARRANTIES

Except as expressly set forth in this Agreement, NEITHER UNIVERSAL OR ADAPTIMMUNE MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTIBILITY, FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF BIOLOGICAL MATERIAL, MODIFICATIONS, AND/OR LICENSED PRODUCT(S) WILL NOT INFRINGE ANY PATENT, COPYRIGHT, OR TRADEMARK, OR OTHER RIGHTS OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.

### 5. Release, Indemnification, and Insurance

5.1 <u>Adaptimmune's Release</u>. For itself and its employees, Adaptimmune hereby releases University and its regents, employees, and agents forever from any suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of (i) the manufacture, use, lease, sale, or other disposition of a Licensed Product; (ii) the assigning or sublicensing of Adaptimmune's rights under this Agreement; or (iii) manufacture or use of Modifications and/or Licensed Products by Service Partners.

5.2 <u>Adaptimmune's Indemnification</u>. Throughout the term of this Agreement and thereafter, Adaptimmune shall indemnify, defend, and hold University and its regents, employees, and agents harmless from all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), relating to or arising out of the manufacture, use, lease, sale, or other disposition of Biological Materials, Modifications, and/or Licensed Product(s), including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to a Licensed Product and claims brought by a SubAdaptimmune or Service Partner.

# 5.3 Adaptimmune's Insurance.

- 5.3.1 <u>General Insurance Requirement</u>. Throughout the term of this Agreement, or during such period as the Parties shall agree in writing, Adaptimmune shall maintain, and shall cause each Sub-Licensee to maintain, in full force and effect commercial general liability (CGL) insurance, with single claim limits consistent with industry standards. Such insurance policy will include coverage for claims that may be asserted by Universal against Adaptimmune under section 6.2 "Adaptimmune's Indemnification". Adaptimmune shall deliver to Universal a copy of the certificate of insurance for such policy following receipt of written request for such.
- 5.3.2 <u>Clinical Trial Liability Insurance</u>. On initiation of human clinical trials with respect to Licensed Product(s), Adaptimmune shall provide to Universal certificates evidencing the existence and amount of clinical trials liability insurance, following receipt of request from Universal. Adaptimmune shall further provide Universal, at least annually, proof of continued coverage to the extent such clinical trials are continuing and following receipt of request from Universal.

# 6. Warranties.

6.1 Authority. Each Party represents and warrants to the other Party that it has full corporate power and authority to execute, deliver, and perform this Agreement, and that no other corporate proceedings by such Party are necessary to authorize the Party's execution or delivery of this Agreement.

# 6.2 Disclaimers.

6.2.1 General Disclaimers. EXCEPT FOR THE EXPRESS WARRANTY SET FORTH IN SECTION 11.1 "Authority" OF THIS AGREEMENT, UNIVERSAL DISCLAIMS AND EXCLUDES ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH BIOLOGICAL MATERIAL AND MODIFICATIONS AND EACH LICENSED PRODUCT, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

- 7.1 Remedy Limitation. EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, IN NO EVENT SHALL UNIVERSITY BE LIABLE FOR (A) PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT OR (B) LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OF ANY KIND.
- 7.2 <u>Damage Cap.</u> IN NO EVENT WILL UNIVERSITY'S TOTAL LIABILITY FOR THE BREACH OR NONPERFORMANCE OF THIS AGREEMENT EXCEED [\*\*\*]. THIS LIMITATION WILL APPLY TO CONTRACT, TORT, AND ANY OTHER CLAIM OF WHATEVER NATURE.

# 8. NAMES AND MARKS

Nothing contained in this Agreement shall be construed as conferring any right to use any name, trade name, trademark, service mark, symbol or other designation of the other party, or the name of any faculty member, employee, or student of the other party, without prior written consent of that party, unless such listing is required under local laws or regulations, provided that either party may state the existence of this Agreement. For any use other than the foregoing, the parties hereby expressly agree not to use the other party's name or the University's name or any contraction, abbreviation, or simulation thereof without prior written approval from an authorized representative of the relevant entity.

# 9. TERMINATION

9.1 Adaptimmune may terminate this Agreement by giving Universal notice in writing at least 30 days in advance of the effective termination date provided that Adaptimmune, Sublicencees, and Service Partners shall thereupon cease use and sale of Biological Material and any Licensed Product(s).

# 9.2 Effect of Termination

- 9.2.1 <u>Licensed Terminated</u> After termination of this Agreement, Adaptimmune shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products.
- 9.2.2 Concurrent with notice of termination by either Adaptimmune or Universal, Adaptimmune and Service Partners shall destroy all Modifications, and Licensed Product(s) in their possession, and shall

provide written evidence of said destruction. If Adaptimmune enters into a direct license with Universal to retain rights in the Modifications under Section 10.2.3

- 9.2.3 "Termination of Elf Licence.", Adaptimmune may retain Modifications and Licensed Product(s) in its possession during the Initial Notice Period and negotiation period. At any time within 30 days following termination of the Elf Licence (notification of which to be immediately provided by Universal to Adaptimmune), Adaptimmune may notify Universal and University that it wishes to enter into a direct license with University in order to retain its rights to the Modifications granted to it under this Agreement (such 30-day period following termination, the "Initial Notice Period"). Following receipt of such notice, University and Adaptimmune (and to the extent required Universal shall facilitate such negotiations and finalization) shall enter into a license agreement the terms of which shall be substantially similar to the terms of the Elf Licence; and the scope of such direct license, the licensed territory or the duration of the license grant shall be comparable to the corresponding terms granted to Adaptimmune under this Agreement; provided that Adaptimmune will be granted at least the same scope of rights as it obtained from Universal under this Agreement. For the sake of clarity, the financial terms, including without limitation, the running royalty rate and milestone payments, shall be identical to the corresponding financial terms set forth in the Elf Licence. Universal shall keep Adaptimmune informed of all material changes to the Elf Licence, including changes to the financial terms that Adaptimmune would be required to accept under this Section. Notwithstanding the foregoing, each Adaptimmune's right to enter into such direct license shall be conditioned upon:
  - 10.2.3.1 <u>Written Notification to University</u>. Adaptimmune informing Universal and University in writing, pursuant to Article 11.4 "Notices", that it wishes to enter into such direct license with University, within the Initial Notice Period;
  - 10.2.3.2 <u>Adaptimmune Good Standing</u>. Adaptimmune being in good standing with Universal under this Agreement, and this Agreement not being the subject of a dispute between Adaptimmune and Universal, or between Universal and University under the Elf Licence (in which case Universal shall have notified Adaptimmune of such dispute);
  - 10.2.3.3 <u>Valid Sublicense</u>. This Agreement having been validly entered into by Adaptimmune and Universal pursuant to the terms of the Elf Licence and the parties confirm and agree that this Agreeent has been validly entered into pursuant to the terms of the Elf Licence;
  - 10.2.3.4 <u>Certification that Conditions Satisfied</u>. Adaptimmune using reasonable efforts to certify or otherwise demonstrate that the conditions set forth in the above subsections subsections have been met within 30 days of expiration of the Initial Notice Period (or within such longer period of

time as University agrees is reasonable under the circumstances, based on the nature and extent of any documentation reasonably requested by University); and

- 10.2.3.5 <u>Time Limitations</u>. Such negotiations for a direct license not exceeding 90 days from the end of the 30-day (or longer, if applicable) period described in subsection 9.2.3.2 "Adaptimmune Certification that Conditions Satisfied" (subject to extension of said 90-day period by mutual written agreement of University and Adaptimmune). University may, at its sole discretion, waive any of these requirements. If all of the conditions set forth in this Subsection 9.2.3 "Termination of Sublicenses" are met, then Adaptimmune will be granted such direct license by University. If any condition set forth in this Section 10.2.3 "Termination of Sublicenses" is not met, then after expiration of any time period granted to Adaptimmune with respect to meeting such condition, Adaptimmune shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products and University shall be free to license or not license Licensed Patents to such Adaptimmune according to its sole discretion. Adaptimmune shall destroy all Modifications and Licensed Product(s) in their possession, and shall provide written evidence of said destruction.
- 9.3 <u>Breach by Adaptimmune</u>. Universal may terminate this Agreement if Adaptimmune is in breach of any provision hereof and Adaptimmune fails to remedy any such breach no later than 60 days after written notice thereof by Universal.
- 9.4 <u>Survival</u>. Immediately upon the termination of this Agreement all Adaptimmune's rights under this Agreement will terminate; provided, however, That the obligations and rights set forth in Sections 11.7 "Records Retention", 11.8 "Audit Rights" and 10.2 "Effect of Termination" and Articles 6 "Release, Indemnification, and Insurance", 7 "Warranties", 8 "Damages", 11.2 "Public Records Act", 11.6 "Law and Venue" will survive the termination of this Agreement.

# 10. MISCELLANEOUS

- 10.1 Adaptimmune Compliance With All Laws Adaptimmune shall comply and ensure that any Service Partners shall comply with all applicable laws, statutes, regulations, guidelines and reporting requirements in all applicable jurisdictions in its use, storage, disposal, handling, transferring and selling of Biological Material and/or Licensed Product(s).
- 10.2 Assignment Adaptimmune shall not assign this Agreement to a Third Party without the express written consent of Universal, except that Adaptimmune may assign or otherwise transfer this Agreement and the license granted hereby and the rights acquired by it hereunder so long as such assignment or transfer is

accompanied by a sale or other transfer of Adaptimmune's entire business or of the entirety of that part of Adaptimmune's business to which the license granted hereby relates, including a change of control. Adaptimmune shall provide written notice to Universal of such assignment and transfer no later than 10 days after the close of the transaction pursuant to which such assignement is made. Upon such assignment or transfer, the term "Adaptimmune" as used in this Agreement will include such assignee or transferee and this Agreement will be binding upon Adaptimmune's permitted successors and assigns. Any attempted assignment, transfer or delegation in breach of this provision will be deemed void and will entitle Universal to terminate this Agreement upon written notice to Adaptimmune.

10.3 Notices - All notices under this Agreement will be deemed to have been fully given when done in writing and deposited in the United States mail, registered or certified, and addressed as follows:

If to University: UW Center for Commercialization

Attn: Director, Technology Licensing 4311 11th Avenue NE, Suite 500 Seattle, WA 98105-4608

Facsimile No.: 206-685-4767 (Universal shall keep Adaptimmune informed of any changes to notification address for

University)

If to Universal: Attn: Claudia Mitchell, CEO

Universal Cells, Inc 720 Broadway Seattle, WA 98122 E-mail: [\*\*\*]

If to

Attn: Helen Tayton-Martin, COO

Adaptimmune:

Adaptimmune Limited, 101 Park Drive, Milton Park

Abingdon, Oxford, OX14 4RY

E-mail: [\*\*\*] with a copy to legal@adaptimmune.com.

Either party may change its address upon written notice to the other party.

- 10.4 Waiver and Severability None of the terms of this Agreement can be waived except by the written consent of the party waiving compliance. If any provision of this Agreement is held illegal, void, or unenforceable, the remaining portions will remain in full force and effect.
- 10.5 <u>Law and Venue</u> The laws of the state of Washington will govern the validity, construction, and enforceability of this Agreement, without giving effect to the conflict of laws principles thereof. Any claim related in any manner to this Agreement will be instituted and commenced in, and venue will be either King County, Washington or the United States District Court for the Western District of Washington.
- 10.6 <u>Record Retention</u>- Throughout the term of this Agreement and for 5 years thereafter, Adaptimmune, at its expense, shall keep and maintain complete and accurate records of all sales, leases, and other dispositions of Licensed Products during the term of this Agreement and all other records related to this Agreement.
- 10.7 <u>Audit Rights</u> Adaptimmune shall, at the request of Universal, permit one or more accountants selected exclusively by University to have access to Adaptimmune's records and books of account pertaining to this Agreement during ordinary working hours to audit with respect to any payment period ending prior to such request, the correctness of any report or payment made under this Agreement.

The accountant will not disclose to University or Universal any information relating to the business of Adaptimmune except that which is necessary to inform University of: the accuracy or inaccuracy of Adaptimmune's reports and payments; compliance or noncompliance by Adaptimmune with the terms and conditions of this Agreement; and the extent of any inaccuracy or noncompliance.

University will bear the costs of any audit initiated by Universal.

- 10.8 Export Controls Adaptimmune shall abide by all U.S. export laws and regulations. Accordingly, Adaptimmune is solely responsible for securing any necessary permissions or licenses to exercise its rights under this Agreement.
- 10.9 Entire Agreement No Third Party Beneficiaries. This Agreement (including all attachments, exhibits, and amendments hereto) is intended by the parties as the final and binding expression of their contract and agreement and as the complete and exclusive statement of the terms thereof. This Agreement cancels, supersedes, and revokes all prior negotiations, representations and agreements among the parties, whether oral or written, relating to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

<u>Adaptimmune</u>	<u>Universal Cells</u>		
By:	By:		
Name:	Name:		
Title:	Title:		
Date:	Date:		
	<del></del> -	_	

# <u>Schedule 4 — Universal Pre-existing Patents</u>

Title	Status	Application Number	Country	Filing Date
Adeno-Associated Viruses (AAV) Isolates and AAV Vectors Derived Therefrom	Issued/Granted	08/873,168	US	6/11/1997
Targeted Gene Modification by Parvoviral Vectors	Converted	60/044,789	US	4/24/1997
Targeted Gene Modification by Parvoviral Vectors	Nationalized	PCT/US98/07964	WO	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Converted	60/106,191	US	10/28/1998
Targeted Gene Modification by Parvoviral Vectors Targeted Gene Modification by Parvoviral Vectors	Issued/Granted Issued/Granted	72521/98 2,289,277	AU CA	4/20/1998 4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Validated	98919818.9	EP	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Nationalized	PCT/US99/25462	WO	10/27/1999
Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	10/423,604	US	4/24/2003
Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	FR	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	DE	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	СН	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	IE	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	GB	4/20/1998
Targeted Gene Modification by Parvoviral Vectors	Pending	13/114,117	US	5/24/2011
TARGETED GENE MODIFICATION BY PARVOVIRAL VECTORS	Pending	2,797,661	CA	4/20/1998
HLA Homozygous Cells and Methods of Use Thereof	Converted	60/905,966	US	3/9/2007
HLA Homozygous Cells and Methods of Use Thereof	Issued/Granted	12/044,471	US	3/7/2008
HLA HOMOZYGOUS CELLS	Issued/Granted	13/333,010	US	12/21/2011
METHODS FOR IMPROVING THE EFFICIENCY OF GENE TARGETING	Pending	1301125.9	GB	1/22/2013
Methods for Improving the Efficiency of Gene Targeting	Pending	PCT/GB2014/050173	WO	1/22/2014
Beta-2 microglobulin-deficient human cells	Converted	61/477,474	US	4/20/2011
BETA-2 MICROGLOBULIN-DEFICIENT CELLS	Nationalized	PCT/US2012/034051	WO	4/18/2012
BETA-2 MICROGLOBULIN-DEFICIENT CELLS	Pending	14/111,837	US	10/15/2013
BETA-2 MICROGLOBULIN-DEFICIENT CELLS	Pending	2,833,173	CA	4/18/2012
BETA-2 MICROGLOBULIN-DEFICIENT CELLS	Pending	12720040.0	EP	4/18/2012
Beta-2 microglobulin-deificient human cells	Pending	Not available	JP	4/18/2012
HLA CLASS II DEFICIENT CELLS	Converted	61/625,314	US	4/17/2012
HLA CLASS II DIFICIENT CELLS, HLA CLASS I DEFICIENT CELLS CAPABLE OF EXPRESSING HLA CLASS II PROTEINS, AND USES THEREOF	Pending	PCT/US2013/032058	WO	3/15/2013
Controlling stem cell potential	Converted	62/012,539	US	6/16/2014

## EXCLUSIVE PATENT LICENSE AND MATERIAL TRANSFER AGREEMENT

**BETWEEN** 

## **UNIVERSAL CELLS**

AND

## UNIVERSITY OF WASHINGTON

**FOR** 

INVENTIONS AND MATERIALS RELATED TO OR USEFUL FOR ADENO-ASSOCIATED VIRUS (AAV)-MEDIATED GENE TARGETING AND HLA ENGINEERING

**UW REF. 34243A** 

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#### EXCLUSIVE PATENT LICENSE AND MATERIAL TRANSFER AGREEMENT

This exclusive patent license and material transfer agreement ("Agreement") is dated and effective as of the date of last signature (the "Effective Date"), and is made between the University of Washington, a public institution of higher education and an agency of the state of Washington, acting through its Center for Commercialization, Technology Licensing ("University"), and Universal Cells, a Corporation under the laws of the state of Washington ("Company"), (individually "Party" or collectively "Parties").

#### **Background**

Certain inventions and materials related to or useful for adeno-associated virus (AAV)-mediated gene targeting and HLA engineering were made in the laboratory of David Russell ("Principal Investigator") or for the materials, in the laboratory listed in Exhibit D "Materials";

As assignee of the inventions, University owns certain patents and patent applications or jointly owns with a Third Party "Joint Owner" certain patents and patent applications, as listed in Section A1 "Licensed Patents" of Exhibit A "Patent License Schedule", and University has the right to license to others certain rights to such patents and patent applications;

The "Joint Owner" of certain patents and patent applications, as listed in Section A1 "Licensed Patents" of Exhibit A, retains their own rights in jointly owned Licensed Patents, and University is only licensing its own interest;

University's rights in certain patents and patent applications listed in Section A1 "Licensed Patents" of Exhibit A "Patent License Schedule" have been licensed to a third party prior to this Agreement on a co-exclusive basis, as defined below;

Company desires that University grant it a license to use, develop, and commercialize the Licensed Products; and

University is willing to grant a license on the terms set forth below.

The Parties therefore agree as follows:

#### 1. Definitions.

For purposes of interpreting this Agreement, the following terms have the following meanings ascribed to them:

1.1. "Acquisition" means (i) the sale by Company of all but no less than all of its assets to an arm's length Third Party, (ii) the sale, transfer, or exchange by the shareholders, partners, or equity owners of Company of a majority interest in Company to an arm's length Third Party, or (iii) the merger of Company into an arm's length Third Party.

- 1.3. "Co-exclusive" for the purposes of this Agreement means, other than as provided for in Section 3.2 "The United States Government's Rights", and Section 3.3 "University's Reservation of Rights", University will only grant licenses to a maximum of two separate parties.
- 1.4. "Group 2 Scope" means co-exclusive for the construction, sale and use of cell lines derived from Stem Cells using Group 2 Licensed Patents specifically for: i) in vitro discovery and development of pharmaceutical agents; ii) in vitro discovery, development and validation of diagnostic targets; and iii) in vitro development of engineered cell lines for bioproduction of pharmaceutical agents; exclusive for the development and use of therapeutic products where the construction or manufacture of the therapeutic product itself utilized Group 2 Licensed Patents.
- 1.5. "Confidential Information" means any information or materials (biological, chemical, or otherwise) of the Parties not generally known to the public, including any information comprised of those materials, and including without limitation the inventions covered by the Licensed Patents and Company's business plans or reports. Confidential Information does not include any information that:

- 1.5.1. is or becomes part of the public domain through no fault of receiving Party;
- 1.5.2. is known to receiving Party prior to the disclosure by the disclosing Party, as evidenced by documentation;
- 1.5.3. is publicly released as authorized under this Agreement by University, its employees or agents;
- 1.5.4. is subsequently obtained by a Party from a Third Party who is authorized to have such information; or
- 1.5.5. is independently developed by a Party without reliance on any portion of the Confidential Information received from the disclosing Party and without any breach of this Agreement as evidenced by documentation.
- 1.6. "Event of Force Majeure" means an unforeseeable act that wholly prevents a Party from performing one or more of its material duties under this Agreement and that is outside of the reasonable control of the Party. An Event of Force Majeure includes acts of war or of Nature, insurrection and riot, and labor strikes. An Event of Force Majeure does not mean a Party's inability to obtain a Third Party's consent to any act or omission.
  - 1.7. "Fair Market Value" means [\*\*\*]

.

1.8. "Product Family 1" means Licensed Products that are vectors or cell lines for research and development purposes. "Product Family 2" means Licensed Products in a therapeutic.

- 1.9. "Fields of Use" means all Fields of Use for Group 1 Licensed Patents, Group 3 Licensed Patents; and the Group 2 Scope for Group 2 Licensed Patents.
- 1.10. "Fully-Diluted Shares " means the total number of Shares outstanding assuming the exercise or conversion of all securities convertible into Shares.
- 1.11. "Licensed Materials" means the materials provided by University to Company that are listed on Exhibit D "Materials" attached hereto, and includes any Licensed Materials contained within materials derived by Company from Licensed Materials.
- 1.12. "Licensed Patents" means the patents and patent applications (including all provisional, nonprovisional, and PCT patent applications, and all national stage and foreign equivalents of the foregoing, accordingly) listed in Section A1 "Licensed Patents" of attached Exhibit A "Patent License Schedule", all divisionals and continuations of these patent applications, all patents issuing from these applications, divisionals, and continuations and any reissues, reexaminations and extensions of these patents. Claims in continuations-in-part applications are included in Licensed Patents only to the extent such claims are supported by a patent or patent application set forth in Section A1 "Licensed Patents" of Exhibit A "Patent License Schedule" to benefit from the priority date of such patent or patent application and to the extent such claims are not encumbered by Third Party rights.
- 1.13. "Licensed Product" means any product or good or service that is used, made by, made for, sold, transferred, offered for sale, imported or otherwise disposed of during the term of this Agreement and for which use, manufacture, sale, transfer is covered by one or more Valid Claims of the Licensed Patents.

1.14. [\*\*\*]

- 1.15. "Patent Expenses" means all reasonable costs (including attorneys' and application fees) incurred by University to apply for, prosecute, enforce, and maintain Licensed Patents including the costs of interferences, oppositions, re-examinations, and patent litigation. For clarity, patent litigation may result in a positive cash position from damages and therefore is subject to distribution rights of the Parties of Article 7 "Infringement".
  - 1.16. [\*\*\*].
  - 1.17. [\*\*\*] .
  - 1.18. "Shares" means the Company's common stock.
- 1.19. "Sublicense" means the grant by Company or a Sublicensee to a Third Party of any license, option, first right to negotiate, or other right granted under the Licensed Patents and/or Licensed Materials, in whole or in part. For the avoidance of doubt, any arm's length Third Party distributor ("Distributor") to which Company or any of its Sublicensees sells a Licensed Product for resale of Licensed Product by the Distributor, and where Distributor has no other rights other than to resell Licensed Product, and for which resale Company and Sublicensees receive no further consideration (including but not limited to royalties and/or commissions) beyond the price for the initial sale to the Distributor shall not be a considered a Sublicensee.
  - 1.20. "Sublicensee" means a Third Party holding a Sublicense under the Licensed Patents.
  - 1.21. "Sublicensing Consideration" means [\*\*\*]
  - 1.22. "Territory" means worldwide.
  - 1.23. "Third Party" means an individual or entity other than University and Company.

1.24. "Valid Claim" means (i) a claim in an issued and unexpired patent included in the Licensed Patents that: (a) has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, and not subject to appeal, (b) has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, (c) has not been lost through an interference, reexamination, or reissue proceeding; or (ii) a pending claim of a pending patent application included in the Licensed Patents.

#### 2. Term.

The term of this Agreement will commence on the Effective Date and, unless terminated earlier as provided in Article 9 "Termination", will expire on the date on which no Valid Claim in a Licensed Patent is pending or subsisting in any country in the Territory.

#### 3. Grant of License.

#### 3.1. Company's Rights.

- 3.1.1. <u>License Grant for Group 1 Licensed Patents</u>. Subject to the terms and conditions of this Agreement, University hereby grants to Company, and Company hereby accepts, a non-exclusive license under University's rights in Group 1 Licensed Patents to make, have made on Company's behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products in the Territory in the Field of Use.
- 3.1.2. <u>License Grant for Group 2 Licensed Patents</u>. Subject to the terms and conditions of this Agreement, University hereby grants to Company, and Company hereby accepts, a license with scope restricted co-exclusivity and scope restricted exclusivity as defined in Group 2 Scope, under University's rights in Group 2 Licensed Patents to make, have made on Company's behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products in the Territory in the Field of Use.

- 3.1.3. <u>License Grant for Group 3 Licensed Patents</u>. Subject to the terms and conditions of this Agreement, University hereby grants to Company, and Company hereby accepts, an exclusive license under University's rights in Group 3 Licensed Patents to make, have made on Company's behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products in the Territory in the Field of Use.
- 3.1.4. <u>License Grant for Licensed Materials</u>. Subject to the terms and conditions of this Agreement, University hereby grants to Company, and Company hereby accepts, a non-exclusive license under University's rights in Licensed Materials to use the Licensed Materials in research and development activities related to the Licensed Products, and in the creation of Licensed Products. For avoidance of doubt, Company is not granted the right to use Licensed Materials other than in the development of Licensed Product, or in the construction or manufacture of Licensed Product.
- 3.1.5. <u>Sublicenses</u>. Company has the right, exercisable from time to time during the term of this Agreement, to Sublicense its (i) exclusive and co-exclusive rights under this Agreement and (ii) non-exclusive rights under this agreement, but only for the purpose of combining the practice of the non-exclusive rights with the practice of the sublicensed exclusive or co-exclusive rights. Company may not grant Sublicensees the right to enforce Licensed Patents. Company shall remain responsible for its obligations under this Agreement, and shall ensure that the Sublicense agreement: a) contains terms and conditions requesting Sublicensee to comply with the applicable terms and conditions under this Agreement (including a release substantially similar to that provided by Company in Section 10.1 "Company's Release"; a warranty substantially similar to that provided by Company in Section 11.1 "Authority"; University disclaimers and exclusions of warranties under Sections 11.3 "Disclaimers"; and limitations of remedies and damages substantially similar to those provided by Company in Sections 12.1 "Remedy Limitation" and 12.2 "Damage Cap"); and (b) specifically incorporates provisions of this Agreement regarding obligations pertaining to indemnification, use of names and insurance. Company shall deliver to University a true, correct, and complete copy of any Sublicense agreement or other agreement under which Company grants Sublicense rights, within 30 days of its execution. Company shall not enter into such agreement if the terms of the agreement are inconsistent in any respect with the material terms of this Agreement. Any Sublicense made in violation of this Subsection will be void and will constitute an event of default under Subsection 9.1.1 "Breach by Company".

- 3.1.6. The license granted in this Agreement is limited to the inventions that are expressly claimed in the Licensed Patents. No provision of this Agreement grants Company, by implication, estoppel or otherwise, any rights other than the rights expressly granted it in this Agreement to the Licensed Patents, Licensed Materials, or to any other University-owned technology, materials, patent applications, or patents.
- 3.2. The United States Government's Rights. The inventions covered in the Licensed Patents arose, in whole or in part, from federally supported research and the federal government of the United States of America has certain rights in and to the Licensed Patents as those rights are described in Chapter 18, Title 35 of the United States Code and accompanying regulations, including Part 401, Chapter 37 of the Code of Federal Regulation. The Parties' rights and obligations under this Agreement to any government-funded inventions, including the grant of license set forth in Subsections 3.1.1 "License Grant for Group 1 Licensed Patents", 3.1.2 "License Grant for Group 2 Licensed Patents" and 3.1.3 "License Grant for Group 3 Licensed Patents" are subject to the aforementioned United States laws.
- 3.3. <u>University's Reservation of Rights</u>. University reserves all rights not expressly granted to Company under this Agreement. University retains for itself an irrevocable, nonexclusive license to make, have made, and use products, processes, and other subject matter covered by the Licensed Patents or Licensed Materials in the Field of Use for academic research, medical, instructional, or any other academic purpose. Expressly included within this University reservation of rights is the right (i) to use the Licensed Patents in sponsored research or collaborative research with any Third Party but only to the extent no such Third Party is granted any rights to the Licensed Patents or to commercialize Licensed Products, (ii) to grant material transfer agreements to materials whose composition of matter is covered by the Licensed Patents where the use of such materials is restricted to academic research, medical, instructional, or any other academic purpose, and (iii) to publish any information included in the Licensed Patents or any other information that may result from University's research.

3.4. Delivery of Licensed Materials. [\*\*\*]

- 3.5. <u>Mandatory Sublicensing</u>. If University is solicited by a Third Party who wishes to license Licensed Patents for any field within the Field of Use that Company is not diligently pursuing (hereinafter "Third Party Field"), University shall so notify Company, and Company shall notify University in writing of the following: (i) whether Company has been engaged in Sublicensing negotiations with such Third Party, (ii) the terms of such Sublicense offered by Company to such Third Party, and (iii) the length of time over such negotiations have occurred. Company shall exercise one of the following options within 90 days of Company's receipt of University's notification:
  - 3.5.1. <u>Company Development Plan.</u> Provide University with a reasonable rationale as to why offering the a sublicense in Third Party Field would be competitive with market opportunity Company is either actively pursuing, or planning on pursuing; or
  - 3.5.2. <u>Company Grant</u>. Offer to grant a Sublicense to said soliciting Third Party in the Third Party Field on commercially reasonable license terms.
  - 3.5.3. <u>University Direct Grant.</u> If Company has not proceeded under either Subsection 3.5.1 "Company Development Plan" or 3.5.2 "Company Grant" within 90 days of notification to Company by University, University may directly grant a license to such Third Party in the Third Party Field for the benefit of University exclusive of any benefit to Company.

#### 4. Applications and Patents.

4.1. <u>Pre-Agreement Patent Filings and Licensed Product Sales</u>. Company has reviewed the Licensed Patents and has no basis to challenge or dispute the inventorship, validity, or enforceability of any of the claims made in the Licensed Patents in existence as of the Effective Date. Company further represents that, as of the Effective Date, it has not and does not manufacture, have manufactured, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of (i) any product or good that infringes (including under the doctrine of equivalents) a claim in any Licensed Patent, or (ii) any product or good that is made using a process or machine that infringes (including under the doctrine of equivalents) a claim in a Licensed Patent.

#### 4.2. Patent Application Filings during the Term of this Agreement.

4.2.1. <u>University Prosecutes Patents</u>. University retains the sole and exclusive right to file or otherwise prosecute Licensed Patents. As set out in Section A4 "Patent Cost Reimbursement" of Exhibit A "Patent License Schedule", Company shall pay, or reimburse University for paying, all Patent Expenses incurred prior to, on, or after the Effective Date.

#### 4.2.2. Patent Prosecution Decisions.

- 4.2.2.1. Exclusive Group 3 Patents: University, in consultation with Company, shall determine in which countries University will file, or cause to be filed, Licensed Patents for Group 3 License Patents. University shall request patent counsel to inform Company of the status of the prosecution of the Licensed Patents, including delivering to Company written and electronic communications from all patent offices and foreign counsel, and University shall consult with the Company on the prosecution of the Licensed Patents. Once Company begins reimbursing University for Patent Expenses pursuant to Section A4 "Patent Cost Reimbursement" of Exhibit A "Patent License Schedule", Company's suggestions and requests regarding patent prosecution will be reasonably considered and included unless detrimental to University's intellectual property rights. In no event shall Company file a patent application where all of the inventors are under University policy obligated to assign their rights in such patent application to University policy obligated to assign their rights in such patent application to University without providing University prior notification of such filing.
- 4.2.2.2. <u>Co-Exclusive Group 2 Licensed Patents</u>: University shall determine in which countries University will file, or cause to be filed, Licensed Patents for Group 2 Licensed Patents. University shall request patent counsel to inform Company of the status of the prosecution of the Licensed Patents, including delivering to Company written and electronic communications from all patent offices and foreign counsel, and University shall seek input from the Company on the prosecution of the Licensed Patents. Once Company begins reimbursing University for Patent Expenses pursuant to Section A4 "Patent Cost Reimbursement" of Exhibit A "Patent License Schedule", Company's suggestions and requests regarding patent prosecution will be reasonably considered and included unless detrimental to University's intellectual property rights, or in conflict with reasonable suggestions from the other licensee of Licensed Patents. In no event shall Company file a patent application where all of the inventors are under University policy obligated to assign their rights in such patent application to University. In no event shall Company file a patent application where one or

more, but not all, of the inventors are under University policy obligated to assign their rights in such patent application to University without providing University prior notification of such filing..

- 4.2.3. <u>University's Independent Patent Filings</u>. At its sole expense, University may file, prosecute or maintain Licensed Patents in any country in which Company has not requested University to file, prosecute or maintain such Licensed Patents in accordance with this Article 4 "Applications and Patents" and those applications and resultant patents will not be subject to this Agreement.
- 4.2.4. <u>No Limitation on University's Right to Prosecute Patents</u>. No provision of this Agreement limits, conditions, or otherwise affects University's right to prosecute Licensed Patents in any country, except as expressly provided herein.
- 4.3. <u>Maintenance of Licensed Patents</u>. Subject to Company's compliance with Section A4 "Patent Cost Reimbursement" of attached Exhibit A "Patent License Schedule", University shall take all commercially reasonable steps to cause each Licensed Patent to remain or be valid and subsisting.
- 4.4. Ownership of the Licensed Patents. No provision of this Agreement grants Company any rights, titles, or interests (except for the grant of license in Subsections 3.1.1 "License Grant for Group 1 Licensed Patents", 3.1.2 "License Grant for Group 2 Licensed Patents" and 3.1.3 "License Grant for Group 3 Licensed Patents" of this Agreement) in the Licensed Patents, notwithstanding Company's payment of all or any portion of the patent prosecution, maintenance, and related costs.

#### 5. Commercialization.

5.1. <u>Commercialization and Performance Milestones</u>. Company shall use its commercially reasonable efforts, consistent with sound and reasonable business practices and judgment, to commercialize the inventions covered by the Licensed Patents and to make and sell Licensed Products as soon as practicable and to maximize sales thereof. [\*\*\*]

- 5.2. <u>Covenants Regarding the Manufacture of Licensed Products</u>. Company hereby covenants and agrees that the manufacture, use, sale, or transfer of Licensed Products will comply with all applicable federal and state laws, including all federal export laws and regulations. Company hereby further covenants and agrees that, to the extent required by 35 United States Code Section 204, it shall, and it shall cause each Sublicensee, to substantially manufacture in the United States of America all products embodying or produced through the use of an invention that is subject to the rights of the federal government of the United States of America.
- 5.3. Commercialization Reports. Throughout the term of this Agreement and within [\*\*\*] of the [\*\*\*], Company shall deliver to University written reports of Company's and Sublicensees' efforts and plans to commercialize the inventions covered by the Licensed Patents and to make, have made on its behalf, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products. Company shall not be obligated to prepare such commercialization reports in years Company or Sublicensee delivers to University a written sales report under Section 6.4 "Sales Reports" and will resume if sales of Licensed Products ceases. In relation to each of the performance milestones described in Section A2 "Performance Milestones" of attached Exhibit A "Patent License Schedule", each commercialization report will include sufficient information to demonstrate compliance of those performance milestones and will set out timeframes and plans for those which have not yet been met. Company shall also include a current capitalization chart to indicate the number of Shares University owns in Company, and total number of Shares and Fully Diluted Shares.
- 5.4. <u>Use of University's Name and Trademarks or the Names of University Faculty, Staff, or Students</u>. No provision of this Agreement grants Company or Sublicensee any right or license to use the name or trademarks of University or the names or identities of any member of the faculty, staff, or student body of University. Company shall not use, and shall not permit a Sublicensee to use, any such trademarks, names, or identities without University's and, as the case may be, such member's prior written approval.

#### 6. Payments, Reimbursements, Reports, and Records.

- 6.1. <u>Payments</u>. Company shall deliver to University the payments specified in Sections A3 "Payments" and A4 "Patent Cost Reimbursement" of attached Exhibit A "Patent License Schedule". Company shall make such payments by check, wire transfer, or any other mutually agreed-upon and generally accepted method of payment. All checks to University will be made payable to "University of Washington" and will be mailed to the address specified in Article 21 "Notices" of this Agreement and will include the University agreement number 34243A. Upon request, University shall deliver to Company written wire transfer instructions.
- 6.2. <u>Currency and Checks</u>. All computations and payments made under this Agreement will be in United States dollars. The exchange rate for the currency into dollars as reported in the *Wall Street Journal* (Western Edition) as the New York foreign exchange mid-range rate on the last business day of the month in which the transaction was entered into will be used for determining the dollar value of transactions conducted in non-United States dollar currencies.
- 6.3. <u>Late Payments</u>. University may charge Company a late fee for all amounts owed to University that are overdue by 30 days or more. The late fee will be computed as [\*\*\*] plus [\*\*\*]%, compounded monthly, as set forth by *The Wall Street Journal* (Western edition) of the outstanding, unpaid balance. The payment of a late fee will not foreclose or limit University from exercising any other rights it may have as a consequence of the lateness of any payment.
- 6.4. <u>Sales Reports</u>. Within 30 days after the last day of each calendar quarter commencing the calendar quarter after Company effects its first commercial sale of a Licensed Product and during the term of this Agreement, Company shall deliver to University a written sales report (a copy of the form of which is attached as Exhibit B "Royalty Report Form") recounting the number and Net Sales (expressed in U. S. dollars) of all sales, leases, or other dispositions of Licensed Products, whether made by Company or a Sublicensee, during such calendar quarter. Included in each sales report will be the name of each Distributor, and the number and type of Licensed Product sold, leased, or otherwise provided to such Distributor. Company shall deliver such written report to University even if Company is not required hereunder to pay to University a payment for sales, leases, or other dispositions of Licensed Products during the calendar quarter.

#### 6.5. Records Retention and Audit Rights.

- 6.5.1. <u>Records Retained</u>. Throughout the term of this Agreement and for 5 years thereafter, Company, at its expense, shall keep and maintain and shall cause each Sublicensee to keep and maintain complete and accurate records of all sales, leases, and other dispositions of Licensed Products during the term of this Agreement and all other records related to this Agreement.
- 6.5.2. <u>Auditing Rights</u>. Company shall permit, at the request of University, one or more accountants selected exclusively by the University ("Accountants") to have access to Company's records and books of account pertaining to this Agreement, but not more than once per calendar year. Accountants' access will be during ordinary working hours to audit Company's records for any payment period ending prior to such request, the correctness of any report or payment made under this Agreement, or to obtain information as to the payments due for any period in the case of failure of Company to report or make payment pursuant to the terms of this Agreement or to verify Company's compliance with its payment obligations hereunder. Company shall cause each Sublicensee that manufactures, sells, leases, or otherwise disposes of Licensed Products on behalf of Company to grant University the right to inspect and audit Sublicensee's records.
- 6.5.3. <u>Scope of Disclosure</u>. Accountants shall not disclose to University any information relating to the business of Company except that which is necessary to inform University of: (i) the accuracy or inaccuracy of Company's reports and payments; (ii) compliance or noncompliance by Company with the terms and conditions of this Agreement; and (iii) the extent of any inaccuracy or noncompliance.
- 6.5.4. <u>Accountant Copies</u>. If Accountants believe there is an inaccuracy in any of Company's payments or noncompliance by Company with any terms and conditions, Accountants shall have the right to make and retain copies (including photocopies) of any pertinent portions of the records and books of account.
- 6.5.5. <u>Costs of Audit</u>. If Company's royalties calculated for any calendar year quarterly period are under-reported by more than 5%, the costs of any audit and review initiated by University will be borne by Company; otherwise, University shall bear the costs of any audit initiated by University.

#### 7. Infringement.

- 7.1. Third-Party Infringement of a Licensed Patent.
- 7.1.1. <u>Notice of Third Party's Infringement</u>. If a Party learns of substantial, credible evidence that a Third Party is infringing a Licensed Patent in the Field of Use in the Territory, that Party will promptly deliver written notice of the possible infringement to the other Party, describing in detail all relevant information to which that Party has access or control suggesting infringement of the Licensed Patent.
- 7.1.1. Company's First Right to Settle. During the term of this Agreement, Company has the first right to respond to, defend, and prosecute in its own name and at its own expense actions or suits relating to exclusively Licensed Patents. To enjoy said first right, Company must initiate bona fide action to respond to any alleged infringement within 90 days of learning of said infringement. If required by law, University agrees to be joined as a party plaintiff; provided that Company must notify University at least 10 days before filing suit and provided that Company shall reimburse University for all reasonable legal fees and costs incident thereto. Company shall not settle any suits or actions in any manner relating to the Licensed Patents without obtaining the prior written consent of University. University will work with Company and Third Party Co-Licensee to determine the best course of action for dealing with infringement of Group 2 Licensed Patents.
  - 7.1.1.1. <u>Distribution of Proceeds from Settlement</u>. Out of any proceeds from any settlement for infringement of Licensed Patents led by Company, Company is allowed to first recover its reasonable attorney's fees and other out-of-pocket expenses directly related to any action, suit, or settlement for infringement of Licensed Patents. Any remaining proceeds will be distributed as follows: Company shall retain [\*\*\*]% and shall distribute [\*\*\*]% to University. Any payment by an alleged infringer that constitutes consideration for Net Sales of infringing product, however, will be handled according to the payment provisions of Article 6 "Payments, Reimbursements, Reports, and Records" and Section A3.1 "Running Royalty Payments" of Exhibit A "Patent License Schedule". Any payment by an alleged infringer that constitutes consideration for the grant of a Sublicense will be handled according to Section A3.8 "Sublicensing Consideration" of Exhibit A "Patent License Schedule".
  - 7.1.1.2. <u>Limitation on Infringement Actions</u>. Excluded from the rights granted herein is the right to bring an infringement action against any inventor or their present or future not-for-profit employers, for infringement of the Licensed Patents in carrying out not-for-profit research.

- 7.1.2. <u>University Right to Institute Action</u>. If Company has first right to pursue infringers and fails, within 90 days of learning of an alleged infringement, to secure cessation of the infringement, institute suit against the infringer, or to provide to University satisfactory evidence that Company is engaged in bona fide negotiations for the acceptance by infringer of a Sublicense in and to relevant patents in Licensed Patents for the Field of Use, then University may, upon written notice to Company, assume full right and responsibility to secure cessation of the infringement, institute suit against the infringer, or secure acceptance of a Sublicense by Company from the alleged infringer in and to relevant patents in Licensed Patents. Such license shall not be subject to Company's approval. If University, in accordance with the terms and conditions of this Agreement, chooses to institute suit against an alleged infringer, University may bring such suit in its own name (or, if required by law, in its and Company's name) and at its own expense, and Company shall, but at University's expense for Company's direct associated expenses, fully and promptly cooperate and assist University in connection with any such suit. All license fees, royalties, damages, awards, or settlement proceeds arising from a University-initiated action will be solely for the account of University.
- 7.1.3. <u>No Obligation to Institute Action</u>. Neither Company nor University is obligated under this Agreement to institute or prosecute a suit against any alleged infringer of Licensed Patents.

#### 8. Patent Validity.

8.1. <u>Notice and Investigation of Third Party Challenges</u>. If any Third Party challenges the validity or enforceability of any of the Licensed Patents, the Party having such information shall immediately notify the other Party.

- 8.2. <u>Tender to University of Third Party Actions</u>. In the event of Third Party legal action challenging the validity or enforceability of any of the Licensed Patents, University, at its sole discretion, shall have the right to assume and control the sole defense of the claim at University's expense. If University opts not to assume and control the sole defense of the claim within 30 days after becoming aware of challenge, Company shall have the right to assume the defense of the claim at its own expense. Company shall not settle any suits or actions in any manner relating to the Licensed Patents without obtaining the prior written consent of University.
- 8.3. <u>Enforceability of Licensed Patents</u>. Notwithstanding challenge by any Third Party, any Licensed Patent will be enforceable under this Agreement until such Licensed Patent is determined to be invalid.

#### 9. Termination.

- 9.1. By University.
- 9.1.1. <u>Breach by Company</u>. If Company breaches or fails to perform one or more of its material duties under this Agreement, University may deliver to Company a written notice of default. University may terminate this Agreement by delivering to Company a written notice of termination if the default has not cured in full within 60 days of the delivery to Company of the notice of default.
- 9.1.2. Events of Default. University may terminate this Agreement by delivering to Company a written notice of termination at least 10 days prior to the date of termination if Company (i) becomes insolvent; (ii) voluntarily files or has filed against it a petition under applicable bankruptcy or insolvency laws that Company fails to have released within 30 days after filing; (iii) proposes any dissolution, composition, or financial reorganization with creditors or if a receiver, trustee, custodian, or similar agent is appointed; (iv) makes a general assignment for the benefit of creditors; or (v) if Company challenges the validity of the Licensed Patents.

9.2. <u>By Company</u>. Company may terminate this Agreement at any time by delivering to University a written notice of termination at least 60 days prior to the effective date of termination.

#### 9.3. Effect of Termination.

- 9.3.1. <u>License Terminated</u>. After termination of this Agreement, Company shall destroy Licensed Materials, and Company shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products.
- 9.3.2. <u>Final Report to University</u>. Within 60 days after the end of the calendar quarter following the expiration or termination of this Agreement, Company shall submit a final report to University. Any payments, including those incurred but not yet paid (such as the pro-rata minimum annual royalty, and those related to patent expense incurred as of the date of termination but not yet paid), due to University shall become immediately due and payable upon termination or expiration.
- 9.3.3. Termination of Sublicenses. At any time within 30 days following termination of this Agreement, a Sublicensee may notify University that it wishes to enter into a direct license with University in order to retain its rights to the Licensed Patents and/or Licensed Materials granted to it under its Sublicense (such 30-day period following termination, the "Initial Notice Period"). Following receipt of such notice, University and Sublicensee shall enter into a license agreement the terms of which shall be substantially similar to the terms of this Agreement; and the scope of such direct license, the licensed territory or the duration of the license grant shall be comparable to the corresponding terms granted by the Company to such Sublicensee; provided that such Sublicensee will be granted at least the same scope of rights as it obtained from Company under its Sublicense. For the sake of clarity, the financial terms, including without limitation, the running royalty rate and milestone payments, shall be identical to the corresponding financial terms set forth in this Agreement. Notwithstanding the foregoing, each Sublicensee's right to enter into such direct license shall be conditioned upon:

- 9.3.3.1. <u>Written Notification to University</u>. Such Sublicensee informing University in writing, pursuant to Article 21 "Notices", that it wishes to enter into such direct license with University, within the Initial Notice Period;
- 9.3.3.2. <u>Sublicensee Good Standing</u>. Such Sublicensee being in good standing with Company under its Sublicense, and such Sublicense not being the subject of a dispute between Sublicensee and Company, or between Company and University under this Agreement;
- 9.3.3.3. <u>Valid Sublicense</u>. Such Sublicense having been validly entered into by Company and Sublicensee pursuant to the terms of Section 3.1.5 "Sublicenses";
- 9.3.3.4. <u>Sublicensee Certification that Conditions Satisfied</u>. Such Sublicensee using reasonable efforts to certify or otherwise demonstrate that the conditions set forth in subsections 9.3.3.1 "Written Notification to University", 9.3.3.2 "Sublicensee Good Standing", and 9.3.3.3 "Valid Sublicense" have been met within 30 days of expiration of the Initial Notice Period (or within such longer period of time as University agrees is reasonable under the circumstances, based on the nature and extent of any documentation reasonably requested by University); and
- 9.3.3.5. <u>Time Limitations</u>. Such negotiations for a direct license not exceeding 90 days from the end of the 30-day (or longer, if applicable) period described in subsection 9.3.3.4 "Sublicensee Certification that Conditions Satisfied" (subject to extension of said 90-day period by mutual written agreement of University and Sublicensee).

University may, at its sole discretion, waive any of these requirements. If all of the conditions set forth in this Section 9.3.3 "Termination of Sublicenses" are met, then Sublicensee will be granted such direct license by University. If any condition set forth in this Section 9.3.3 "Termination of Sublicenses" is not met, then after expiration of any time period granted to Sublicensee with respect to meeting such condition (for example and to the extent applicable, the Initial Notice Period and/or the periods described in Subsections 9.3.3.4 "Sublicensee Certification that Conditions Satisfied" and 9.3.3.5 "Time Limitations"), Sublicensee shall not make, have made, use, offer to sell or sell, offer to

lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products and University shall be free to license or not license Licensed Patents to such Sublicensee according to its sole discretion.

#### 10. Release, Indemnification, and Insurance.

- 10.1. <u>Company's Release</u>. For itself and its employees, Company hereby releases University and its regents, employees, and agents forever from any suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of (i) the manufacture, use, lease, sale, or other disposition of a Licensed Product or Licensed Material; or (ii) the assigning or sublicensing of Company's rights under this Agreement.
- 10.2. <u>Company's Indemnification</u>. Throughout the term of this Agreement and thereafter, Company shall indemnify, defend, and hold University and its regents, employees, and agents harmless from all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), relating to or arising out of the manufacture, use, lease, sale, or other disposition of a Licensed Product or Licensed Materials, including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to a Licensed Product or Licensed Materials and claims brought by a Sublicensee.

#### 10.3. Company's Insurance.

10.3.1. General Insurance Requirement. Throughout the term of this Agreement, or during such period as the Parties shall agree in writing, Company shall maintain, and shall cause each Sublicensee to maintain, in full force and effect commercial general liability (CGL) insurance, with single claim limits consistent with industry standards. Such insurance policy will include coverage for claims that may be asserted by University against Company under section 10.2 "Company's Indemnification". Such insurance policy must name the Board of Regents of the University of Washington as an additional insured and will require the insurer to deliver written notice to University at the address set forth in Article 21 "Notices" of this Agreement, at least 45 days prior to the termination of the policy. Company shall deliver to University a copy of the certificate of insurance for such policy.

10.3.2. <u>Clinical Trial Liability Insurance</u>. Within 30 days prior to the initiation of human clinical trials with respect to Licensed Products, Company shall provide to University certificates evidencing the existence and amount of clinical trials liability insurance. Company shall issue irrevocable instructions to its insurance agent and to the issuing insurance company to notify University of any discontinuance or lapse of such insurance not less than 45 days prior to the time that any such discontinuance is due to become effective. Company shall provide University a copy of such instructions upon their transmittal to the insurance agent and issuing insurance company. Company shall further provide University, at least annually, proof of continued coverage.

#### 11. Warranties.

- 11.1. <u>Authority</u>. Each Party represents and warrants to the other Party that it has full corporate power and authority to execute, deliver, and perform this Agreement, and that no other corporate proceedings by such Party are necessary to authorize the Party's execution or delivery of this Agreement.
  - 11.2 <u>University Representation and Warranty</u>. University represents and warrants that:
  - 11.2.1 it has sufficient rights, title and interests of the Licensed Patents and Licensed Materials to grant the licenses to Company as purported to be granted pursuant to this Agreement
  - 11.2.2 Joint Owner has agreed to allow University to license University's rights in co-owned Licensed Patents with a scope and territory as described in this Agreement.

#### 11.3. Disclaimers.

11.3.1. <u>General Disclaimers</u>. EXCEPT FOR THE EXPRESS WARRANTY SET FORTH IN SECTION 11.1 "Authority" OF THIS AGREEMENT, UNIVERSITY DISCLAIMS AND EXCLUDES ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH LICENSED PATENT AND EACH LICENSED PRODUCT, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-

# INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

- 11.3.2. <u>Patent Disclaimers</u>. University expressly disclaims any warranties concerning and makes no representations:
  - 11.3.2.1. Patent Issuance. That the Licensed Patents will be approved or will issue;
  - 11.3.2.2. Licensed Patent Validity/Scope. Concerning the validity or scope of any Licensed Patent; or
  - 11.3.2.3. <u>Non-Infringement</u>. That the manufacture, use, sale, lease or other disposition of a Licensed Product or Licensed Material will not infringe a Third Party's patent or violate a Third Party's intellectual property rights.

#### 12. Damages.

- 12.1. Remedy Limitation. EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, IN NO EVENT SHALL UNIVERSITY BE LIABLE FOR (I) PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT AND (II) AND IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OF ANY KIND.
- 12.2. <u>Damage Cap</u>. IN NO EVENT WILL UNIVERSITY'S TOTAL LIABILITY FOR THE BREACH OR NONPERFORMANCE OF THIS AGREEMENT EXCEED [\*\*\*]
- . THIS LIMITATION WILL APPLY TO CONTRACT, TORT, AND ANY OTHER CLAIM OF WHATEVER NATURE.

#### 13. Amendment and Waiver.

This Agreement may be amended from time to time only by a written instrument signed by the Parties. No term or provision of this Agreement will be waived and no breach excused unless such waiver or consent will be in writing and signed by the Party claimed to have waived or consented. No waiver of a breach will be deemed to be a waiver of a different or subsequent breach.

#### 14. Assignment.

The rights and licenses granted by University in this Agreement are personal to Company and Company shall not assign its interest or delegate its duties under this Agreement without the written consent of University; any such assignment or delegation made without written consent of University will not release Company from its obligations under this Agreement. The preceding sentence notwithstanding, Company, without the prior approval of University, may assign all, but no less than all, its rights and delegate all, but no less than all, its duties under this Agreement to a Third Party provided that:

- (i) the assignment is made to such Third Party as a part of and in connection with (a) the sale by Company of all but no less than all of its assets to the Third Party, (b) the sale, transfer, or exchange by the shareholders, partners, or equity owners of Company of a majority interest in Company to the Third Party, or (c) the merger of Company into the Third Party (each of the events described in part (a), (b) or (c) of this paragraph, an "Acquisition"),
- (ii) Company obtains from such Third Party written agreement to honor all obligations under this Agreement accrued by Company before Acquisition and all obligations under this Agreement to accrue by such Third Party assignee after Acquisition, including any and all financial obligations, and
- (iii) no later than 10 days after the close of the transaction pursuant to which such Acquisition is made, Company shall provide written notice to University of the Acquisition, as well as a substitution of parties document, in which such Third Party assignee assumes responsibility for all of Company's

outstanding and future obligations relating to this Agreement. Any assignment made in violation of this Article will be void and will, without further act, cause the immediate termination of this Agreement, effective retroactively to the date of the Acquisition.

This Agreement will inure to the benefit of Company and University and their respective permitted assignees and trustees.

#### 15. Confidentiality.

- 15.1. <u>Form of transfer.</u> Confidential Information may be conveyed in tangible or intangible form. Disclosing Party must clearly mark its Confidential Information "confidential." If disclosing Party communicates Confidential Information in non-written form, it shall reduce such communications to writing, clearly mark it "confidential", and provide a copy to receiving Party within 30 days of original communication at the address in Article 21 "Notices".
- 15.2. No Unauthorized Disclosure of Confidential Information. Beginning on the Effective Date and continuing throughout the term of this Agreement and thereafter for a period of 5 years, receiving Party shall not disclose or otherwise make known or available to any Third Party any disclosing Party Confidential Information, without the express prior written consent of disclosing Party. Notwithstanding the foregoing, receiving Party shall be permitted to disclose disclosing Party Confidential Information to (i) actual or potential investors, lenders, consultants, collaborators, Sublicensees, or development partners, which disclosure will be made under conditions of confidentiality and limited use and (ii) its attorney or agent as reasonably required. In no event shall receiving Party incorporate or otherwise use disclosing Party's Confidential Information in connection with any patent application filed by or on behalf of receiving Party. Receiving Party shall restrict the use of disclosing Party's Confidential Information exclusively to the terms of this Agreement. Receiving Party shall use reasonable procedures to safeguard disclosing Party's Confidential Information. In the case where Company is the receiving Party, Company's confidentiality obligations will also apply equally to Sublicensees.
- 15.3. Access to University Information. University is an agency of the state of Washington and is subject to the Washington Public Records Act, RCW 42.56 et seq., ("Act"), and no obligation assumed by University under this Agreement shall be deemed to be inconsistent with University's obligations as defined under the Act and as interpreted by University in its sole discretion. If

University receives a request for public records under the Act for documents containing Company Confidential Information, and if University concludes that the documents are not otherwise exempt from public disclosure, University will provide Company notice of the request before releasing such documents. Such notice will be provided in a timely manner to afford Company sufficient time to review such documents and/or seek a protective order, at Company's expense utilizing the procedures described in RCW 42.56.540. University shall have no obligation to protect Company Confidential Information from disclosure in response to a request for public records.

15.4. <u>Disclosure as Required by Law</u>. Either Party shall have the right to disclose the other Party's Confidential Information as required by law or valid court order, provided that such Party shall inform the Party who owns such Confidential Information prior to such disclosure and shall limit the scope and recipient of disclosure to the extent required by such law or court order.

#### 16. Consent and Approvals.

Except as otherwise expressly provided, all consents or approvals required under the terms of this Agreement must be in writing and will not be unreasonably withheld or delayed.

#### 17. Construction.

The headings preceding and labeling the sections of this Agreement are for the purpose of identification only and will not in any event be employed or used for the purpose of construction or interpretation of any portion of this Agreement. As used herein and where necessary, the singular includes the plural and vice versa, and masculine, feminine, and neuter expressions are interchangeable.

## 18. Enforceability.

If a court of competent jurisdiction adjudges a provision of this Agreement unenforceable, invalid, or void, such determination will not impair the enforceability of any of the remaining provisions hereof and the provisions will remain in full force and effect.

## 19. No Third-Party Beneficiaries.

No provision of this Agreement, express or implied, confers upon any person other than the Parties to this Agreement any rights, remedies, obligations, or liabilities hereunder. No Sublicensee shall have a right to enforce or seek damages under this Agreement.

## 20. Language.

Unless otherwise expressly provided in this Agreement, all notices, reports, and other documents and instruments that a Party hereto elects or is required by the terms of this Agreement to deliver to the other Party hereto will be in English.

#### 21. Notices.

All notices, requests, and other communications that a Party is required or elects to deliver will be in writing and will be delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other Party at its address set forth below or to another address as a Party may designate by notice given pursuant to this article:

If to University: UW Center for Commercialization

ATTN: Director, Technology Licensing

4311 11th Avenue NE, Suite 500

Seattle, WA 98105-4608

Facsimile No.: 206-685-4767

If to Company: Attn: Claudia Mitchell, CEO

Universal Cells, Inc

2219 East Howe St

Seattle, WA 98112

Facsimile No.: 425-242-0469

E-mail: [\*\*\*]

### 22. Patent Marking.

Company shall mark all material forms of Licensed Product(s) or packaging pertaining thereto made and sold by Company in the United States with patent marking conforming to 35 U.S.C. §287(a), as amended from time to time. Such marking shall further identify the pendency of any United States patent application and/or any issued United States or foreign patent forming any part of the Licensed Patents. All Licensed Product(s) shipped to or sold in other countries will be marked in such a manner as to provide notice to potential infringers pursuant to the patent law and practice of the country of manufacture or sale.

#### 23. Publicity.

University shall have the right to report in its customary publications and presentations that University and Company have entered into a license agreement for the technology covered by the Licensed Patents and University

may use Company logos in such publications and presentations provided that University does not modify Company's logos and does not through such use imply any endorsement by Company of University.

The Parties will cooperate with one another to review and respond to any press release or similar communication proposed by the other Party regarding the non-confidential subject matter of this Agreement. The specific content and timing of such press releases or similar communication is subject to mutual agreement by the Parties, which will not be unreasonably withheld. Further, University and Company shall issue a joint press release regarding this Agreement, subject to both Party's review and approval of the specific content thereof, and such press release shall include specific mention of the contributions of University personnel and University in developing the technology in a prominent portion of the press release. Company shall provide University with appropriate quotes for such press release. University may post the press release in digital and print publications as well as on University's own website.

#### 24. Relationship of Parties.

In entering into, and performing their duties under, this Agreement, the Parties are acting as independent contractors and independent employers. No provision of this Agreement shall create or be construed as creating a partnership, joint venture, or agency relationship between the Parties. No Party shall have the authority to act for or bind the other Party in any respect.

#### 25. Relationship with Principal Investigator.

Company acknowledges that Principal Investigator is employed by University and has certain pre-existing obligations to University, including obligations with respect to disclosure and ownership of intellectual property and obligations arising from sponsored research agreements between University and Third Parties. Accordingly, Company agrees that to the extent that any consulting agreement is inconsistent with any of Principal Investigator's obligations to University, including the reporting of all inventions developed while employed by University (regardless of where arising) and including contractual obligations arising under any sponsored research agreements between University and Third Parties, then Principal Investigator's obligations to University shall prevail and to

such extent any inconsistent provisions of this consulting agreement shall be deemed inapplicable and unenforceable.

#### 26. Security Interest.

In no event shall Company grant, or permit any person to assert or perfect, a security interest in Licensed Patents or in Company's rights under this Agreement.

#### 27. Survival.

Immediately upon the termination or expiration of this Agreement all Company's rights under this Agreement will terminate; provided, however, Company's obligations that have accrued prior to the effective date of termination or expiration of this Agreement (e.g., the obligation to report and make payments on sales, leases, or dispositions of Licensed Products and to reimburse University for costs) and the obligations specified in Sections 6.1 "Payments" and 6.4 "Sales Reports" will survive. The obligations and rights set forth in Sections 6.5 "Records Retention and Audit Rights" and 9.3 "Effect of Termination" and Articles 10 "Release, Indemnification, and Insurance", 11 "Warranties", 12 "Damages", 15 "Confidentiality", 29 "Applicable Law" and 30 "Forum Selection" will survive the termination or expiration of this Agreement.

#### 28. Collection Costs and Attorneys' Fees.

If a Party fails to perform an obligation or otherwise breaches one or more of the terms of this Agreement, the other Party may recover from the non-performing breaching Party all its costs (including actual attorneys' and investigative fees) to enforce the terms of this Agreement.

#### 29. Applicable Law.

The internal laws of the state of Washington will govern the validity, construction, and enforceability of this Agreement, without giving effect to the conflict of laws principles thereof.

#### 30. Forum Selection.

A suit, claim, or other action to enforce the terms of this Agreement will be brought exclusively in the state and federal courts of King County, Washington. Company hereby submits to the jurisdiction of that court and waives any objections it may have to that court asserting jurisdiction over Company or its assets and property.

## 31. Entire Agreement.

This Agreement (including all attachments, exhibits, and amendments) is the final and complete understanding between the Parties concerning licensing the Licensed Patents. This Agreement supersedes any and all prior or contemporaneous negotiations, representations, and agreements, whether written or oral, concerning the Licensed Patents. This Agreement may not be modified in any manner, except by written agreement signed by an authorized representative of both Parties.

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be duly executed by their respective authorized representatives.

Unive	ersity of Washington	Unive	rsal Cells
By:	/s/ Fiona White	By:	/s/ Claudia Mitchell
Name	: Fiona White, Ph.D. MBA	Name:	Claudia Mitchell
Title:	Director of Technology Licensing	Title:	CEO
Date:	06/27/14	Date:	06/27/14

## Exhibit A

## **Patent License Schedule**

# A1. Licensed Patents:

A1.1 Group 1 Licensed Patents: Non-exclusive grant

UW#	IP#	Short Title	Status	Application Number	Filing Date	Grant
41571	41571.01US2	AAV Isolates and AAV Vectors	Issued/Granted	08/873,168	6/11/1997	Non- exclusive

# A1.2 Group 2 Licensed Patents

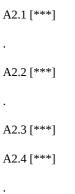
UW#	IP#	Short Title	Status	Application Number	Filing Date	Grant
41754	41754.01US1	Targeted Gene Modification by Parvoviral Vectors	Converted	60/044,789	4/24/1997	Group 2 Licensed Patents Scope
	41754.02WO2	Targeted Gene Modification by Parvoviral Vectors	Nationalized	PCT/US98/07964	4/20/1998	
	41754.03US1	Targeted Gene Modification by Parvoviral Vectors	Converted	60/106,191	10/28/1998	
	41754.04AU2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	72521/98	4/20/1998	
	41754.05CA2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	2,289,277	4/20/1998	
	41754.06EP2	Targeted Gene Modification by Parvoviral Vectors	Validated	98919818.9	4/20/1998	
	41754.10WO2	Targeted Gene Modification by Parvoviral Vectors	Nationalized	PCT/US99/25462	10/27/1999	
	41754.18US4	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	10/423,604	4/24/2003	
	41754.20FR2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.21DE2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.22CH2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.23IE2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.24GB2	Targeted Gene Modification by Parvoviral Vectors	Issued/Granted	98919818.9	4/20/1998	
	41754.25US5	Targeted Gene Modification by Parvoviral Vectors	Pending	13/114,117	5/24/2011	
	41754.26CA3	Targeted Gene Modification by Parvoviral Vectors	Pending	2,797,661	4/20/1998	
45039	45039.01GB2	Methods for Improving the Efficiency of Gene Targeting	Pending	1301125.9	1/22/2013	Jointly owned with third party
	45039.02WO2	Methods for Improving the Efficiency of Gene Targeting	Pending	PCT/GB2014/050173	1/22/2014	Jointly owned with third party

# A1.3 Group 3 Licensed Patents

UW#	IP#	Short Title	Status	Application Number	Filing Date	Grant
43950	43950.01US1	HLA Homozygous Cells and Methods of Use Thereof	Converted	60/905,966	3/9/2007	Exclusive all fields
	43950.02US2	HLA Homozygous Cells and Methods of Use Thereof	Issued/Granted	12/044,471	3/7/2008	
	43950.03US4	HLA Homozygous Cells	Issued/Granted	13/333,010	12/21/2011	
45038	N/A	[***]	Not Filed Yet	N/A	N/A	
45365	45365.01US1	B2M-deficient human cells	Converted	61/477,474	4/20/2011	Exclusive all fields
	45365.02WO2	B2M-deficient human cells	Nationalized	PCT/US2012/034051	4/18/2012	
	45365.03US2	B2M-deficient human cells	Pending	14/111,837	10/15/2013	
	45365.04CA2	B2M-deficient human cells	Pending	2,833,173	4/18/2012	
	45365.05EP2	B2M-deficient human cells	Pending	12720040.0	4/18/2012	
	45365.06JP2	B2M-deficient human cells	Pending	Not available	4/18/2012	
45826	45826.01US1	HLA Class II Deficient Cells	Converted	61/625,314	4/17/2012	Exclusive all fields
46825	46825.01US1	Controlling stem cell potential	Pending	62/012,539	6/16/2014	
46826	N/A	[***]	Not Filed Yet	N/A	N/A	
46895	N/A	[***]	Not Filed Yet	N/A	N/A	

Licensed Patents includes University rights in any patent application that may be filed by University solely on the technology specified in invention disclosures listed above where the patent status is "Not Yet Filed"

**A2. Performance Milestones (Section 5.1 "Commercialization and Performance Milestones"):** Company shall meet the following performance milestones:



A2.5 Company shall, throughout the life of the Agreement, engage in good faith negotiations and efforts to enter into Sublicenses with interested Third Parties.

## A3. Payments (Section 6.1 "Payments"):

A3.1 <u>Running Royalty Payments</u>. For the term of this Agreement, Company shall pay to University a percentage of quarterly Net Sales as a running royalty payment according to the schedule below. Such running royalty payments will be due within 30 days after the last day of each calendar quarter.

A3.1.1. Company shall pay University [\*\*\*]% of Net Sales for Licensed Products sold in Product Family 1 or anything not in Product Family 2;

A3.1.2. Company shall pay University the lesser of [\*\*\*]% of Net Sales of Sublicensee, or [\*\*\*]% of the amount Sublicensee pays Company on Net Sales, for Licensed Products sold in Product Family 2.

A3.2 <u>Minimum Annual Royalties</u>. Company shall pay minimum annual royalties for the term of this Agreement to be creditable against running royalty payments for the preceding calendar year on a non-cumulative basis and to be due in full and payable on January 31st of each year beginning on January 31st of the year following the third anniversary of the Effective Date and continuing during the term of this Agreement according to the following schedule:

```
A3.2.1. $[***] on [***];
A3.2.2. $[***] on [***];
A3.2.3. $[***] on [***]; and
A3.2.4. $[***] on [***] and each [***] thereafter.
```

A3.2.5. If this Agreement is terminated prior to the payment of a minimum annual royalty in any given year the amount due for that minimum annual royalty payment will be prorated on the basis of the number of full quarters that have elapsed prior to termination since the last payment of a minimum annual royalty.

A3.3 <u>Equity</u>. In consideration for the rights granted to Company hereunder, Company shall within 30 days of the Effective Date issue to University, using the Stock Subscription Agreement attached hereto as Exhibit C "Subscription Agreement", Shares equal to [\*\*\*] as of the Effective Date.

A3.3.1. Anti-Dilution Right. [\*\*\*]

A3.4 <u>Third Party Royalties</u>. For Product Family 1, if Company is required to pay royalties to a Third Party based on Company's manufacture, use, or sale of Licensed Product subject to one or more patents of such Third Party then the royalty Company pays to University may be reduced by [\*\*\*]% of the royalty actually paid to the Third Party provided that use of any Third Party patent is required for such manufacture, use, or sale of Licensed Product, and provided that the royalty to the University shall not fall below half of what would otherwise be owed for such Licensed Product based on running royalty due for that Field. Such deduction is not applicable for Product Family 2 or any Licensed Products that are not Product Family 1.

A3.5 <u>Sublicensing Consideration</u>. Within [\*\*\*] days of the end of every [\*\*\*] (ie. [\*\*\*] per [\*\*\*]) during the term of this Agreement, Company shall pay to University a percentage of all Sublicensing Consideration received by Company during such calendar quarter as set out below. A reduction of the percentage of Sublicensing Consideration payable to University under this Agreement will be negotiated in good faith between the Parties where, in addition to the Sublicense of any rights granted to Company hereunder, Company also grants Sublicensee a license under a Third Party's intellectual property rights, which license is necessary for Sublicensee to manufacture, have manufactured, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Product(s) without infringing such Third Party's intellectual property rights provided, and only to the extent that the total aggregate consideration for such combined license is treated as Sublicensing Consideration.

A3.5.1. [\*\*\*]

A3.5.2. [\*\*\*]

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A3.5.3. [\*\*\*]

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A3.5.4. [\*\*\*]

A3.5.5. [\*\*\*]

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A3.5.6. [\*\*\*]

A3.5.7. Company and University will negotiate in good faith whether to waive the requirement that the milestone be reached prior to execution to the Sublicense to reduce the percentage due to University where Company provides information satisfactory to University to demonstrate Company is a necessary and integral partner in development of such Licensed Product with Sublicensee, and contributed significantly to meeting the Sublicensing Consideration reducing milestone.

A3.6 <u>Acquisition Fee</u>. Within [\*\*\*] days of any assignment of rights granted to Company under this Agreement, Company shall pay to University [\*\*\*]% of any Acquisition consideration received by Company, provided this amount will be decreased according to the following schedule provided the Acquisition is executed after the milestone has been met for each level:

A3.6.1. [\*\*\*]% after Company has executed at least one revenue generating Sublicense or partnership agreement for the Licensed Patents.

A3.6.2. [\*\*\*]% after Company has raised at least \$[\*\*\*] in dilutive funding.

**A4. Patent Cost Reimbursement**: Company shall pay, or reimburse University for paying, all Patent Expenses incurred prior to, on, or after the Effective Date according to the schedule below and within 30 days of its receipt of University's invoice for such Patent Expenses. University reserves the right to

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request advance payments for certain Patent Expenses, at University's discretion. The amount of Patent Expenses invoiced to University prior to the Effective Date is over US \$[\*\*\*]. For Licensed Patents licensed to more than one party, Company will pay a pro rata share of Patent Expenses based on the number of licensees for any given Licensed Patent.

A4.1 Company will begin paying ongoing Patent Expenses immediately following a Qualified Financing or the second anniversary of the Effective Date, whichever is sooner.

A4.2 Company will pay unreimbursed Patent Expenses, whether incurred prior to the Effective Date, or after the Effective Date but before either a Qualified Financing or the second anniversary of the Effective Date, in three equal installments, the first installment due immediately following a Qualified Financing or the second anniversary of the Effective date, whichever is sooner, the second installment due one year after the first installment, and the third installment due two years after the first installment.

# Exhibit B

# **Royalty Report Form**

Date			
Company Name & Address			
License Number			
Reporting Period:		- Report Due Date:	
This report must be submitte	ed regardless of whether royalties are	e owed.	
Please do not leave any colur	nn blank. State all information reque	ested below.	
Product Description	Royalty Rate	Quantity/ Net Sales	Royalty Due
Report Completed by:		Total Royalties Due:	
Telephone Number:			
If you have questions		-	
please contact:		-	

Please make check payable to: University of Washington			

#### **Exhibit C**

#### SUBSCRIPTION AGREEMENT

SUBSCRIPTION AGREEMENT, dated the date indicated below on the signature page hereof, by and between the Company and the University. If and when accepted by the Company, this Subscription Agreement, when executed below, shall constitute a subscription for that number of shares of the Securities indicated on the attached Appendix A. All capitalized terms are defined on Appendix A.

INTENDING TO BE LEGALLY BOUND, and in consideration of the mutual representations, warranties, covenants and agreements contained herein, Company and University hereby agree as follows:

- 1. <u>Representations and Warranties of the University</u>. The University hereby represents and warrants to the Company as of the date of this Agreement as follows:
- 1.1 The University: (a) is an Accredited Investor as that term is defined in 17 CFR § 230.501(a); (b) has been furnished with all information deemed necessary by the University to evaluate the merits and risks of the Securities; (c) has had the opportunity to ask questions and receive answers concerning the Company and the Securities; and (d) has been given the opportunity to obtain any additional information necessary to verify the accuracy of any information obtained concerning the Company.
- 1.2 <u>Ability to Bear Risk</u>. The University is in a financial position to hold the Securities and is able to bear the economic risk and withstand a complete loss of the investment in the Securities.
- 1.3 <u>Risk Factors</u>. The University recognizes that the Securities as an investment involve an extremely high degree of risk. There can be no assurance that the Company will be able to meet its projected goals and the Company may need significant additional capital to be successful, which capital may not be readily

available or available upon terms that are not substantially dilutive to the University. If provided, the University has reviewed the risk factors description provided by the Company.

- 1.4. <u>Sophistication</u>. The University is a sophisticated investor, is able to fend for itself in the transactions contemplated by this Agreement, and has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the prospective investment in the Securities.
- 1.5. <u>Suitability</u>. The investment in the Securities is suitable for the University based upon its investment objectives and financial needs, and the University has adequate net worth and means for providing for its current financial needs and contingencies and has no need for liquidity of investment with respect to the Securities.
- 1.6. <u>Overall Commitment to Illiquid Investments</u>. The University's overall commitment to investments which are illiquid or not readily marketable is not disproportionate to its net worth, and investment in the Securities will not cause such overall commitment to become excessive.
- 1.7. <u>Restricted Securities</u>. The University realizes that (i) none of the Securities have been registered under the Securities Act of 1933, as amended (the "Act"), (ii) the Securities are characterized under the Act as "restricted securities" and, therefore, cannot be sold or transferred unless they are subsequently registered under the Act or an exemption from such registration is available and (iii) there is presently no public market for the Securities and the University may not be able to liquidate his investment in the event of an emergency or pledge the Securities as collateral security for loans. In this connection, the University represents that it is familiar with Rule 144 promulgated under the Act, and understands the resale limitations imposed thereby and by the Act.
- 1.8. Exemption Reliance. The University has been advised that the Securities are not being registered under the Act or the applicable state securities laws but are being offered and sold pursuant to exemptions from such laws. The University understands that the Company's reliance on such exemptions is predicated in part upon the truth and accuracy of the University's representations in this Agreement. The University represents and warrants that the Securities are being purchased for its own account, for investment and without the intention of reselling, redistributing or transferring the same, that it has made no agreement with others regarding any of such Securities and that its financial condition is such that it is not likely that it will be necessary to dispose of any of such Securities in the foreseeable future.

- 2. <u>Covenants</u>. The University agrees that:
- 2.1. <u>Transfer Restriction</u>. The Securities for which the University hereby subscribes shall be assigned or transferred only in accordance with all applicable laws.
- 2.2. <u>Disposition of Securities</u>. The University shall in no event make any disposition of all or any portion of the Securities which it is purchasing unless and until:
- a. There is then in effect a registration statement under the Act covering such proposed disposition and such disposition is made in accordance with said registration statement; or
- b. (i) It shall have furnished the Company with an opinion of its own counsel to the effect that such disposition will not require registration of such shares under the Act, and (ii) such opinion of its counsel shall have been concurred in by counsel for the Company, such concurrence not to be unreasonably withheld or delayed, and the Company shall have advised the University of such concurrence; or
- c. The transfer shall comply with the applicable requirements of Rule 144 as promulgated under the Securities Act of 1933, as amended, or is otherwise exempt from the registration requirements of such act.
- 2.3. <u>No Revocation</u>. The University may not cancel, terminate or revoke this subscription, and this subscription shall be binding upon its successors and assigns.
- 2.4 Execution of Related Documents. The University agrees to execute other customary, investment-related agreements as proposed by Company and executed by other investors in Company that contain solely one or more of the following provisions:

$\hfill \Box$ General prohibition on transfer of the Se	ecurities	

☐ Right of first refusal on proposed transfer
☐ Right of co-sale on proposed transfer
[] "Tag along, drag along" rights (both must be included)
☐ Market "standoff" agreements up to 180 days following an initial public offering
provided, however, that such agreements do not discriminate against the University and do not contain any of the following provisions:
☐ Rights to repurchase Securities owned by the University
☐ Vesting requirements applicable to Securities owned by the University
☐ Indemnification obligations by the University
☐ Requirement to vote Securities owned by the University
Penalties on the University, or limitations on the University's rights, as a result of the University's failure to make follow-on investments
Any provision that would apply solely to the University (and not to all other persons who hold the same type and class of Securities as the University)
☐ Confidentiality restrictions or limitations that purport to prevent the University from complying with applicable open records requirements.
3. Intentionally Left Blank
4. <u>Issuance of Stock Certificate</u> . Company agrees to issue and deliver to the University at the Treasury Office address provided in Appendix A a duly-executed stock certificate promptly (and in any case within 30 days) following the execution of this Agreement.

5. <u>Governing Law; Successors</u>. The University agrees that this Subscription Agreement shall be enforced, governed and construed in all respects in accordance with the laws of the State of Washington, that the rights, powers and duties set forth herein shall be binding upon the University, its successors and assigns, and shall inure to the benefit of its successors and assigns.

THE INVESTOR HAS BEEN ADVISED, PRIOR TO ITS PURCHASE OF THE SECURITIES, THAT NEITHER THE OFFERING OF THE SECURITIES NOR ANY OFFERING MATERIALS HAVE BEEN REVIEWED BY ANY ADMINISTRATOR UNDER THE ACT OR ANY OTHER APPLICABLE SECURITIES ACT (THE "ACTS") AND THAT NONE OF THE SECURITIES HAVE BEEN REGISTERED UNDER ANY OF THE ACTS AND THEREFORE CANNOT BE RESOLD UNLESS THEY ARE REGISTERED UNDER THE ACTS OR UNLESS AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.

# SIGNATURE PAGE

acceptan	The University has completed this Agreement as of the date indicated below and understands that this subscription is subject to cceptance by the Company.			
	UNIVER	SITY OF WASHINGTON		
	Ву			
	Title			
	 Dated			

	COMPANY:
Ī	Insert name of Company]
I	Зу
ו	Title
Ι	Dated

#### Appendix A

#### **Defined Terms:**

The following terms shall be defined as follows for purposes of this Agreement:

The term "Agreement" means this Subscription Agreement, when executed by the University and the Company.

The term "Notice" means, with respect to the University, the information required by an applicable section delivered personally, or by facsimile or electronic mail (provided such delivery is confirmed), or by a recognized overnight courier service or by United States mail, first-class, certified or registered, postage prepaid, return receipt requested, to the other Party at its address set forth below or to another address as a Party may designate by notice given pursuant to this article.

The term "Securities" means [\*\*\*] of the [common stock, par value [\*\*\*] per share] [limited liability units] of the Company.

The term "Company" means Universal Cells Inc., a Washington C Corporation .

The term "University" means University of Washington, a public institution of higher education and an agency of the state of Washington, acting through its Center for Commercialization, Technology Licensing.

## **Address for Delivery of Stock Certificate:**

Treasury Office

University of Washington

4311 — 11th Avenue NE, Suite 600 Seattle, WA 98105-4608

With a copy to:

UW Center for Commercialization

University of Washington

4311 — 11th Avenue NE, Suite 500

Seattle, WA 98105

Exhibit D

## Materials

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## CONFIDENTIAL

## NON-EXCLUSIVE LICENSE AGREEMENT

**BETWEEN** 

UNIVERSAL CELLS

AND

UNIVERSITY OF WASHINGTON

FOR

NEW NAIVE HUMAN EMBRYONIC STEM CELL LINE - ELF1

UW #**45910** 

**UWC4C AGREEMENT 35628A** 

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#### NON-EXCLUSIVE LICENSE AGREEMENT

**THIS AGREEMENT** ("Agreement") is dated and effective as of the date of last signature ("Effective Date"), and is made by and between the University of Washington, a public institution of higher education and an agency of the state of Washington acting through its administrative offices at UW Center for Commercialization, 4311 Eleventh Avenue NE, Suite 500, Seattle, WA 98105 ("University"), and Universal Cells, a Corporation under the laws of the state of Washington ("Company"), agree as follows:

#### 1. BACKGROUND

- 1.1 University has certain rights to Biological Material known as New naive human embryonic stem cell line Elf1 (as defined in Section 2.1), developed in the laboratory of Dr. Carol Ware.
- 1.2 University desires to have Biological Material marketed at the earliest possible time in order that products resulting therefrom may be available for public use and benefit.
- 1.3 Company has previously entered into an exclusive license agreement with University for inventions and materials related to or useful for Adeno-associated virus (AAV)-mediated gene targeting and HLA engineering, UW Ref # 34243A on June 27, 2014 "Exclusive Agreement".
- 1.4 Company wishes to acquire a license to said Biological Material to make, use, and sell Licensed Product(s) in the Internal Research Field of Use and Product Field of Use.

#### 2. DEFINITIONS

- 2.1 "Biological Material" means New naive human embryonic stem cell line Elf1 (with a University Reference UW # 45910).
- 2.2 "Internal Research Field of Use" means internal research. Internal Research Field of Use specifically excludes any use which requires regulatory approval, including any in vitro and in vivo diagnostic or therapeutic applications.
- 2.3 "Product Field of Use" means in vivo therapeutics excluding any therapeutic agent for cardiac regeneration and cardiovascular disease.

- 2.4 "Licensed Product" means any product or good or service that is a Modification and is used, made by, made for, sold, transferred, offered for sale, imported or otherwise disposed of during the term of this Agreement..
- 2.5 "Licensed Territory" means worldwide.
- 2.6 "Modifications" means any derivatives or modifications of Biological Material that, but for the rights granted under Exclusive Agreement, would otherwise infringe a Valid Claim of Groups 2 and 3 Licensed Patents as defined in Exclusive Agreement as originally executed. Modifications generated at University and to be provided to Company are listed in Section A1 "UW Materials to be Delivered" in Exhibit A.

2.7 [\*\*\*]

- 2.8 "Product Family 1" means Licensed Products in which Company receives no further consideration (including but not limited to royalties and/or commissions) beyond the price for the initial sale and limited to sales to end-users for research and development purposes. "Product Family 2" means Licensed Products that requires regulatory approval, including any in vitro and in vivo diagnostic or therapeutic applications.
- 2.9 "Service Partner" means a legal entity that is a Third Party with whom Licensee has contracted to provide services within the Internal Research Field of Use and Product Field of Use. For clarity, a legal entity is only a Service Partner for so long as the definition remains true. If such entity terminates its contractual obligation with Licensee, it thereafter is an arm-length Third Party for the purposes of this Agreement.
- 2.10 "Sublicense" means the grant by Company to a Third Party of any license, option, first right to negotiate, or other right granted in the Licensed Products, in whole or in part. For the avoidance of doubt, any sale of a Licensed Product by Company or Sublicensee to an arm's length Third Party distributor ("Distributor") for resale of Licensed Product by the Distributor, and where Distributor has no other rights other than to resell Licensed Product, and for which resale Company and Sublicensees receive no further consideration (including but not limited to royalties and/or commissions) beyond the price for the initial sale to the Distributor shall be considered a sale, and shall not be a considered a Sublicense.
- 2.11 "Sublicensee" means a Third Party holding a Sublicense under the Modifications.
- 2.12 "Sublicensing Consideration" means all consideration, including but not limited to upfront fees, milestone payments, maintenance fees, non-cash consideration, and premiums over Fair Market Value of stock, but excluding royalties, payable by each Sublicensee for the grant of a Sublicense. For avoidance of doubt, consideration paid to Company by Sublicensees for the performance of bona fide product development work, research work, clinical studies and regulatory approvals performed by Company, pursuant to and as supported by an express agreement including a performance plan and commensurate budget is not deemed to be Sublicensing Consideration.

2.13 "Third-Party" means any individual or entity other than University and Company.

#### 3. GRANT

- 3.1 University hereby grants, and Company accepts, a nonexclusive license to make and use Biological Material for Internal Research Field of Use only. Company shall not transfer Biological Material to any Third-Party, including Sublicencee(s) for any purpose.
- 3.2 University hereby grants, and Company accepts, a nonexclusive license in the (i) Product Field of Use and Licensed Territory to make, use, offer, and sell Licensed Product(s) for Product Family 2 and (ii) make, use, offer, and sell Licensed Products in the Internal Research Field of Use for Product Family 1.
- 3.3 Service Partners of Licensee. Licensee shall have the right to transfer Modifications to Service Partners working on behalf of Licensee solely for the purpose of carrying out services in direct connection with using the Modifications in the Internal Field of Use and Product Field of Use. Any such transfer of Modifications to such Service Partner shall be under a written agreement between Licensee and such Service Partner which (a) shall be in writing, (b) shall be subject to, subordinate to, and consistent with, the terms and conditions of this Agreement, (c) shall not adversely affect the rights of University or limit the obligations of Licensee under this Agreement, (d) shall contain terms substantially similar to those contained in this Agreement, and (e) shall expressly provide that the Service Partner has no rights to use the Modifications for any purpose other than to perform the services in direct connection with the Licensed Field of Use, and that such Service Partner shall not transfer the Modifications to any Third-Party. Licensee will be responsible for the performance of all Service Partner in compliance with all obligations of Licensee under this Agreement. For purposes of clarity, Company has no right to transfer Biological Material to Service Partners.
- 3.4 <u>Sublicenses</u>. Company has the right, exercisable from time to time during the term of this Agreement, to Sublicense its rights in the Product Field of Use granted in Paragraph 3.2 of this Agreement, including for evaluation of the suitability of Licensed Products as a therapeutic product for limited time periods

("Evaluation Period"). Said right does not include the right to transfer Licensed Products(s) to Third Parties or affiliates for resale other than as incorporated in a therapeutic product. Company shall remain responsible for its obligations under this Agreement, and shall ensure that the Sublicense agreement: i) contains terms and conditions requesting Sublicensee to comply with the applicable terms and conditions under this Agreement (including a release substantially similar to that provided by Company in Section 6.1 "Company's Release"; a warranty substantially similar to that provided by Company in Section 7.1 "Authority"; University disclaimers and exclusions of warranties under Subsections 7.2 "Disclaimers"; and limitations of remedies and damages substantially similar to those provided by Company in Sections 8.1 "Remedy Limitation" and 8.2 "Damage Cap"); and (ii) specifically incorporates provisions of this Agreement regarding obligations pertaining to indemnification, use of names and insurance. Company shall deliver to University a true, correct, and complete copy of any Sublicense agreement or other agreement under which Company grants sublicensing rights, within 30 days of its execution. Company shall not enter into such agreement if the terms of the agreement are inconsistent in any respect with the material terms of this Agreement. Any Sublicense made in violation of this Subsection will be void and will constitute an event of default under Subsection 10.3 "Breach by Company". For avoidance of doubt, Company has no right to Sublicense Biological Material.

- 3.5 The term of this Agreement shall commence as of the Effective Date and shall expire twenty (20) years from the Effective Date, or when Company does not Sublicense Modifications for four (4) consecutive calendar years, whichever comes sooner, unless sooner terminated according to Article 10 hereunder. The term of the Agreement may be extended by mutual agreement in writing of University and Company.
- 3.6 University retains title to all Biological Material and reserves and retains the right to make and use Biological Material and to grant the foregoing rights to other commercial or non-commercial institutions.
- 3.7 Nothing in this Agreement shall be construed as granting by implication, estoppel, or otherwise any licenses or rights under patents or patent applications of University.

#### 4. PAYMENTS

- 4.1 <u>Payments</u>. Company shall deliver to University the payments specified in Sections A2 "Payments" of attached Exhibit A "UW Materials and Payments". Company shall make such payments by check, wire transfer, or any other mutually agreed-upon and generally accepted method of payment.
- 4.2 <u>Sales Reports</u>. Within [\*\*\*] days after the last day of each calendar quarter, Company shall deliver to University a written sales report (a copy of the form of which is attached as Exhibit B "Royalty Report Form") recounting the number and Net Sales (expressed in U. S. dollars) of all sales, leases, or other dispositions of Licensed Products, whether made by Company or a Sublicensee, during such calendar quarter. Included in each sales report will be the name of each Distributor, and the number and type of Licensed Product sold, leased, or otherwise provided to such Distributor. Company shall deliver such written report to University even if Company is not required hereunder to pay to University a payment for sales, leases, or other dispositions of Licensed Products during the calendar quarter. Included in this report is Sublicensing Consideration received by Sublicensee(s), including consideration received for Evaluation Period by Sublicensee.
- 4.3 University may charge Company a late fee for all amounts owed to University that are overdue by 30 days or more. The late fee will be computed as the [\*\*\*] plus [\*\*\*]%, compounded monthly, as set forth by *The Wall Street Journal* (Western edition) of the outstanding, unpaid balance. The payment of a late fee will not foreclose or limit University from exercising any other rights it may have as a consequence of the lateness of any payment.Company shall make all payments to University in U.S. Dollars, shall mail them to the address specified in Subsection 11.4 Notices, and shall include University License agreement number 35628A. Upon request, University shall deliver to Company written wire transfer instructions.

#### 5. NEGATION OF WARRANTIES

Except as expressly set forth in this Agreement, UNIVERSITY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTIBILITY, FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF BIOLOGICAL MATERIAL, MODIFICATIONS, AND/OR LICENSED PRODUCT(S) WILL NOT INFRINGE ANY PATENT, COPYRIGHT, OR TRADEMARK, OR OTHER RIGHTS OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.

#### 6. RELEASE, INDEMNIFICATION, AND INSURANCE

- 6.1 <u>Company's Release</u>. For itself and its employees, Company hereby releases University and its regents, employees, and agents forever from any suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses) relating to or arising out of (i) the manufacture, use, lease, sale, or other disposition of a Licensed Product; (ii) the assigning or sublicensing of Company's rights under this Agreement; or (iii) manufacture or use of Modifications and/or Licensed Products by Service Partners.
- 6.2 <u>Company's Indemnification</u>. Throughout the term of this Agreement and thereafter, Company shall indemnify, defend, and hold University and its regents, employees, and agents harmless from all suits, actions, claims, liabilities, demands, damages, losses, or expenses (including reasonable attorneys' and investigative expenses), relating to or arising out of the manufacture, use, lease, sale, or other disposition of Biological Materials, Modifications, and/or Licensed Product(s), including, without limitation, personal injury, property damage, breach of contract and warranty and products-liability claims relating to a Licensed Product and claims brought by a Sublicensee or Service Partner.

6.3.1 <u>General Insurance Requirement</u>. Throughout the term of this Agreement, or during such period as the Parties shall agree in writing, Company shall maintain, and shall cause each Sublicensee to maintain, in full force and effect commercial general liability (CGL) insurance, with single claim limits consistent with industry standards. Such insurance policy will include coverage for claims that may be asserted by University against Company under section 6.2 "Company's Indemnification". Such insurance policy must name the Board of Regents of the University of Washington as an additional insured and will require the insurer to deliver written notice to University at the address set forth in Article 11.4 "Notices" of this Agreement, at least 45 days prior to the termination of the policy. Company shall deliver to University a copy of the certificate of insurance for such policy.

6.3.2 <u>Clinical Trial Liability Insurance</u>. Within thirty (30) days prior to the initiation of human clinical trials with respect to Licensed Product(s), Company shall provide to University certificates evidencing the existence and amount of clinical trials liability insurance. Company shall issue irrevocable instructions to its insurance agent and to the issuing insurance company to notify University of any discontinuance or lapse of such insurance not less than 45 days prior to the time that any such discontinuance is due to become effective. Company shall provide University a copy of such instructions upon their transmittal to the insurance agent and issuing insurance company. Company shall further provide University, at least annually, proof of continued coverage.

#### 7. WARRANTIES.

7.1 Authority. Each Party represents and warrants to the other Party that it has full corporate power and authority to execute, deliver, and perform this Agreement, and that no other corporate proceedings by such Party are necessary to authorize the Party's execution or delivery of this Agreement.

#### 7.2 DISCLAIMERS.

7.2.1 General Disclaimers. EXCEPT FOR THE EXPRESS WARRANTY SET FORTH IN SECTION 7.1 "Authority" OF THIS AGREEMENT, UNIVERSITY DISCLAIMS AND EXCLUDES ALL WARRANTIES, EXPRESS AND IMPLIED, CONCERNING EACH BIOLOGICAL MATERIAL AND MODIFICATIONS AND EACH LICENSED PRODUCT, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NON-INFRINGEMENT AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

#### 8. DAMAGES.

- 8.1 <u>Remedy Limitation</u>. EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, IN NO EVENT SHALL UNIVERSITY BE LIABLE FOR (A) PERSONAL INJURY OR PROPERTY DAMAGES ARISING IN CONNECTION WITH THE ACTIVITIES CONTEMPLATED IN THIS AGREEMENT OR (B) LOST PROFITS, LOST BUSINESS OPPORTUNITY, INVENTORY LOSS, WORK STOPPAGE, LOST DATA OR ANY OTHER RELIANCE OR EXPECTANCY, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OF ANY KIND.
- 8.2 <u>Damage Cap.</u> IN NO EVENT WILL UNIVERSITY'S TOTAL LIABILITY FOR THE BREACH OR NONPERFORMANCE OF THIS AGREEMENT EXCEED [\*\*\*]
  - . THIS LIMITATION WILL APPLY TO CONTRACT, TORT, AND ANY OTHER CLAIM OF WHATEVER NATURE.

# 9. NAMES AND MARKS

Nothing contained in this Agreement shall be construed as conferring any right to use any name, trade name, trademark, service mark, symbol or other designation of the other party, or the name of any faculty member, employee, or student of the other party, without prior written consent of that party, unless such listing is required under local laws or regulations, provided that either party may state the existence of this Agreement. For any use other than the foregoing, the parties hereby expressly agree not to use the other party's name or any contraction, abbreviation, or simulation thereof without prior written approval from an authorized representative of the other party.

# 10. TERMINATION

Company may terminate this Agreement by giving University notice in writing at least 30 days in advance of the effective termination date provided that Company, Sublicencees, and Service Partners shall thereupon cease use and sale of Biological Material, Modifications and any Licensed Product(s).

# 10.1 Effect of Termination

- 10.1.1 <u>Licensed Terminated</u> After termination of this Agreement, Company, Sublicencees, ad Service Partners shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products.
- 10.1.2 Concurrent with notice of termination by either Company or University, Company, Sublicensees, and Service Partners shall destroy all Biological Material, Modifications, and Licensed Product(s) in their possession, and shall provide written evidence of said destruction. If Sublicensee enters into a direct license with University to retain rights in the Modifications under Section 10.2.3
- 10.1.3 "Termination of Sublicenses.", Sublicensee may retain Modifications and Licensed Product(s) in their possession during the Initial Notice Period and negotiation period. At any time within 30 days following termination of this Agreement, a Sublicensee may notify University that it wishes to enter into a direct license with University in order to retain its rights to the Modifications granted to it under its Sublicense (such 30-day period following termination, the "Initial Notice Period"). Following receipt of such notice, University and Sublicensee shall enter into a license agreement the terms of which shall be substantially similar to the terms of this Agreement; and the scope of such direct license, the licensed territory or the duration of the license grant shall be comparable to the corresponding terms granted by the Company to such Sublicensee; provided that such Sublicensee will be granted at least the same scope of rights as it obtained from Company under its Sublicense. For the sake of clarity, the financial terms, including without limitation, the running royalty rate and milestone payments, shall be identical to the corresponding financial terms set forth in this Agreement. Notwithstanding the foregoing, each Sublicensee's right to enter into such direct license shall be conditioned upon:
  - 10.2.3.1 <u>Written Notification to University.</u> Such Sublicensee informing University in writing, pursuant to Article 11.4 "Notices", that it wishes to enter into such direct license with University, within the Initial Notice Period;

- 10.2.3.2 <u>Sublicensee Good Standing</u>. Such Sublicensee being in good standing with Company under its Sublicense, and such Sublicense not being the subject of a dispute between Sublicensee and Company, or between Company and University under this Agreement;
- 10.2.3.3 <u>Valid Sublicense</u>. Such Sublicense having been validly entered into by Company and Sublicensee pursuant to the terms of Subsection 3.4 "Sublicenses";
- 10.2.3.4 <u>Sublicensee Certification that Conditions Satisfied</u>. Such Sublicensee using reasonable efforts to certify or otherwise demonstrate that the conditions set forth in Subsections 10.2.3.1 "Written Notification to University", 10.2.3.2 "Sublicensee Good Standing", and 10.2.3.4 "Valid Sublicense" have been met within 30 days of expiration of the Initial Notice Period (or within such longer period of time as University agrees is reasonable under the circumstances, based on the nature and extent of any documentation reasonably requested by University); and

10.2.3.5 <u>Time Limitations</u>. Such negotiations for a direct license not exceeding 90 days from the end of the 30-day (or longer, if applicable) period described in subsection 10.2.3.2 "Sublicensee Certification that Conditions Satisfied" (subject to extension of said 90-day period by mutual written agreement of University and Sublicensee).

University may, at its sole discretion, waive any of these requirements. If all of the conditions set forth in this Subsection 10.2.3 "Termination of Sublicenses" are met, then Sublicensee will be granted such direct license by University. If any condition set forth in this Section 10.2.3 "Termination of Sublicenses" is not met, then after expiration of any time period granted to Sublicensee with respect to meeting such condition (for example and to the extent applicable, the Initial Notice Period and/or the periods described in Subsections 10.2.3.4 "Sublicensee Certification that Conditions Satisfied" and 10.2.3.5 "Time Limitations"), Sublicensee shall not make, have made, use, offer to sell or sell, offer to lease or lease, import, or otherwise offer to dispose or dispose of Licensed Products and University shall be free to license or not license Licensed Patents to such Sublicensee according to its sole discretion. Sublicensee shall destroy all Modifications and Licensed Product(s) in their possession, and shall provide written evidence of said destruction.

- 10.2 Company shall make a written report to University no later than 90 days after the date of termination of this Agreement, stating the number, description, and Net Sales of all Licensed Products ever made, sold, or otherwise disposed of and upon which royalties are payable hereunder but which were not previously reported to University for any reason.
- 10.3 <u>Breach by Company.</u> University may terminate this Agreement if Company is in breach of any provision hereof and Company fails to remedy any such breach no later than 60 days after written notice thereof by University.
- 10.4 <u>Survival</u>. Immediately upon the termination of this Agreement all Company's rights under this Agreement will terminate; provided, however, Company's obligations that have accrued prior to the effective date of

termination of this Agreement (*e.g.*, the obligation to report and make payments on sales, leases, or dispositions of Licensed Products ) and the obligations specified in Sections 4.1 "Payments" and 4.2 "Sales Reports" will survive. The obligations and rights set forth in Sections 11.7 "Records Retention", 11.8 "Audit Rights" and 10.2 "Effect of Termination" and Articles 6 "Release, Indemnification, and Insurance", 7 "Warranties", 8 "Damages", 11.2 "Public Records Act", 11.6 "Law and Venue" will survive the termination of this Agreement.

# 11. MISCELLANEOUS

- 11.1 Company Compliance With All Laws Company shall comply and ensures that any Sublicencees and Service Partners shall comply with all applicable laws, statutes, regulations, guidelines and reporting requirements in all applicable jurisdictions in its use, storage, disposal, handling, transferring and selling of Biological Material and/or Licensed Product(s).
- 11.2 <u>Public Records Act</u>- As an agency of the State of Washington, University is subject to the Washington Public Records Act, RCW 42.56 et seq. ("Act"). No obligation assumed by University under this Agreement shall be deemed to be inconsistent with University's obligations as defined under the Act and as interpreted by University in its sole discretion. In the event University receives a request for public records under the Act for documents containing confidential information, and if University concludes that the documents are not otherwise exempt from public disclosure, University will provide Company notice of the request before releasing such documents. Such notice shall be provided in a timely manner to afford Company sufficient time to review such documents and/or seek a protective order, at Company's expense utilizing the procedures described in RCW 42.56.540. University shall have no obligation to protect the confidential information from disclosure in response to a request for public records.
- 11.3 Assignment Company shall not assign this Agreement to a Third Party without the express written consent of University, except that Company may assign or otherwise transfer this Agreement and the license granted hereby and the rights acquired by it hereunder so long as such assignment or transfer is accompanied by a sale or other transfer of Company's entire business or of the entirety of that part of Company's business to which the license granted hereby relates, including a change of control. Company shall provide written notice to University of such assignment and transfer no later than ten (10) days after

the close of the transaction pursuant to which such assignment is made. Upon such assignment or transfer, the term "Company" as used in this Agreement will include such assignee or transferee and this Agreement will be binding upon Company's permitted successors and assigns. Any attempted assignment, transfer or delegation in breach of this provision will be deemed void and will entitle University to terminate this Agreement upon written notice to Company.

11.4 Notices - All notices under this Agreement will be deemed to have been fully given when done in writing and deposited in the United States mail, registered or certified, and addressed as follows:

If to University: UW Center for Commercialization

Attn: Director, Technology Licensing 4311 11th Avenue NE, Suite 500 Seattle, WA 98105-4608 Facsimile No.: 206-685-4767

If to Company:

Attn: Claudia Mitchell, CEO

Universal Cells, Inc 2219 East Howe St Seattle, WA 98112

Facsimile No.: 425-242-0469

E-mail: [\*\*\*]

Either party may change its address upon written notice to the other party.

11.5 Waiver and Severability - None of the terms of this Agreement can be waived except by the written consent of the party waiving compliance. If any provision of this Agreement is held illegal, void, or unenforceable, the remaining portions will remain in full force and effect.

11.6 <u>Law and Venue</u> - The laws of the state of Washington will govern the validity, construction, and enforceability of this Agreement, without giving effect to the conflict of laws principles thereof. Any claim related in any manner to this Agreement will be instituted and commenced in, and

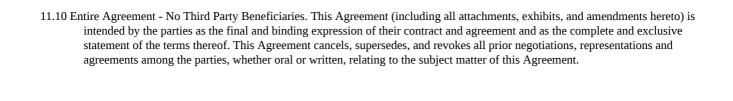
venue will be either King County, Washington or the United States District Court for the Western District of Washington.

- 11.7 <u>Record Retention</u>- Throughout the term of this Agreement and for five (5) years thereafter, Company, at its expense, shall keep and maintain and shall cause each Sublicensee to keep and maintain complete and accurate records of all sales, leases, and other dispositions of Licensed Products during the term of this Agreement and all other records related to this Agreement.
- 11.8 <u>Audit Rights</u> Company shall, at the request of University, permit one or more accountants selected exclusively by University to have access to Company's records and books of account pertaining to this Agreement during ordinary working hours to audit with respect to any payment period ending prior to such request, the correctness of any report or payment made under this Agreement, or to obtain information as to the payments due for any such period in the case of failure of Company to report or make payment according to the terms of this Agreement.

The accountant will not disclose to University any information relating to the business of Company except that which is necessary to inform University of: the accuracy or inaccuracy of Company's reports and payments; compliance or noncompliance by Company with the terms and conditions of this Agreement; and the extent of any inaccuracy or noncompliance.

If the accountant determines that Company's royalties calculated for any quarterly period are under reported by more than five percent (5%), the costs of any audit and review initiated by University will be borne by Company; otherwise, University will bear the costs of any audit initiated by University.

11.9 Export Controls - Company shall abide by all U.S. export laws and regulations. Accordingly, Company is solely responsible for securing any necessary permissions or licenses to exercise its rights under this Agreement.



IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

# **University of Washington**

# **Universal Cells**

By: /s/ Fiona White By: /s/ Claudia Mitchell

Name: Fiona White, Ph.D. MBA

Name: Claudia Mitchell

Title: Director of Technology Licensing Title: CEO

Date: 10/22/14 Date: 10/22/14

### **EXHIBIT A**

# "UW Materials and Payments"

A1. UW Materials to Transfer to Universal Cells	
[***]	
[***]	
[***]	:
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	
[***]	

# A2. Payments (Section 4.1)

- A2.1 Right to Re-negotiate. University hereby grants to Company, the option, but not the obligation to re-negotiate on commercially reasonable terms Section A2 "Payments" upon presenting University an updated business development plan and competitor royalty rates to Biological Material. Upon University's receipt of Company's written notice of intent to exercise this option, University and Company shall enter into good faith discussions to re-negotiate a commercially reasonable royalty rate.
- A2.2 <u>Running Royalty Payments</u>. For the term of this Agreement, Company shall pay to University a [\*\*\*] Net Sales as a running royalty payment according to the schedule below. Such running royalty payments will be due within 30 days after the last day of each calendar quarter.
- A2.2.1 Company shall pay University [\*\*\*]% of Net Sales of Licensed Products sold in Product Family 1, or anything that is not in Product Family 2. This is in addition to any royalties due under the Exclusive Agreement.
- A2.2.2 Company shall pay University [\*\*\*]% of Net Sales for Licensed Products sold in Product Family 2. If Company is able to reduce royalty payments due in Exclusive Agreement per Section A3.1.2 below [\*\*\*]%, Company may reduce the royalty due for Product Family 2 of this Agreement by the same relative percentage. For purposes of clarity, if Company reduces royalty payment by [\*\*\*]

([\*\*\*]%) under Exclusive Agreement, Company may reduce royalty due for Product Family 2 under this Agreement by [\*\*\*] ([\*\*\*]%).

- A2.3 <u>Sublicensing Milestones</u>. Company shall pay to University the following non-cumulative and non-refundable milestone achievement payments within 30 days of achieving the corresponding milestone related to Product Family 2. The below milestones will apply to each Sublicense partner of Company. If Company directly executes a Sublicense without an Evaluation Period, then Milestone A2.3.1 shall not apply.
- A2.3. 1 Evaluation Period. In the event Company receives Sublicensing Consideration for disposition of Licensed Product to Sublicensee for Evaluation only, Company shall pay University [\*\*\*] US Dollars (\$[\*\*\*]) ("Evaluation Fee"). The Evaluation Period shall not exceed one calendar year.
- A2.3.2 <u>Sublicensing Initiation Fee.</u> Company shall pay University [\*\*\*] US Dollars (\$[\*\*\*]) upon execution of each Sublicense agreement, excluding those agreements which fall under Section A2.3.1 "Evaluation Period". For purposes of clarity, execution of a license to Sublicensee after Evaluation Period will require payment of this Milestone Section A2.3.2.
- A2.3.3 <u>Sublicensing Maintenance Fee</u>. Company shall pay University an annual license maintenance fee of [\*\*\*] US Dollars (\$[\*\*\*]) for each Sublicensee agreement "Sublicensing Maintenance Fee", excluding Evaluation agreements as defined in Section A2.3.1, in effect for the preceding [\*\*\*] and to be payable no later than [\*\*\*] of each [\*\*\*] beginning on [\*\*\*] and continuing during the term of this Agreement. Sublicensing Maintenance Fee in any given [\*\*\*] may be prorated on the basis of the number of [\*\*\*] that have elapsed since the execution of each Sublicensing agreement.

# EXHIBIT B

Royalty Report Form

Date			
Company Name & Address			
License Number			
Reporting Period	R	Report Due Date:	
This report must be submitted regardl	ess of whether royalties are owed	l.	
Please do not leave any column blank	. State all information requested b	pelow.	
Product Description	Royalty Rate	Quantity/ Net Sales	Royalty Due
Report Completed by:	Т	Cotally Royalties	
		Due:	
Telephone Number:			
If you have questions please contact:			
Please make check payable to: Univ	versity of Washington		

# <u>Schedule 7 – [\*\*\*]</u>

THIS PAGE AND THE FOLLOWING 6 PAGES OF THIS SCHEDULE HAVE BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

[\*\*\*]

# Schedule 8 – [\*\*\*] Partner Notice

THIS PAGE AND THE FOLLOWING 2 PAGES OF THIS SCHEDULE HAVE BEEN OMITTED AND FI	LED SEPARATELY WITH
THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURIT	TIES EXCHANGE ACT OF
1934, AS AMENDED.	

[\*\*\*]

# CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE

# COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**EXECUTION VERSION** 

# AMENDMENT NO. 1 TO COMMERCIAL DEVELOPMENT AND SUPPLY AGREEMENT and LICENSE AGREEMENT

This Amendment No. 1 to Commercial Development and Supply Agreement ("Amendment No. 1") effective as of 18 November, 2019 ("Amendment No. 1 Effective Date") is entered into by and between ADAPTIMMUNE Limited, with offices at 60 Jubilee Avenue (formerly 101 Park Drive), Milton Park, Abingdon, Oxon, OX14 4RX, England ("ADAPTIMMUNE") and Life Technologies Corporation, an Affiliate of Thermo Fisher Scientific Inc., with offices at 5781 Van Allen Way (formerly 5791), Carlsbad, California 92008 ("LIFE"). and amends the Commercial Development and Supply Agreement effective as of June 1, 2016 entered into by ADAPTIMMUNE and LIFE ("Supply Agreement"). ADAPTIMMUNE and LIFE each hereinafter a "Party" and collectively "Parties".

WHEREAS, the Parties entered into a Commercial Development and Supply Agreement effective as of June 1, 2016 ("Supply Agreement") and also into a License Agreement and Sublicense Agreement effective as of 19 December 2012 (together "License Agreements");

WHEREAS the Parties now wish to amend the terms of the Supply Agreement and License Agreements as specified in this Amendment No. 1.

NOW, THEREFORE, in consideration of the mutual promises contained in this Amendment No. 1 and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

- 1. The following amendments shall be made to the Supply Agreement:
  - a. <u>Amend definition of Development Phase Purchasing Obligation</u>: The definition of "Development Phase Purchasing Obligation" is hereby deleted and replaced in its entirety by the following:

"The minimum purchasing obligation applicable during the Development Phase shall be as follows: [\*\*\*]"

- b. <u>Amend definition of Minimum Purchasing Obligation</u>: The definition of "Minimum Purchasing Obligation" is hereby deleted and replaced in its entirety by the following:
  - "The minimum purchasing obligation is defined by the Development Phase Purchasing Obligation. The minimum purchasing obligation applicable during the Commercial Phase shall be mutually agreed during the Transitional Phase with both Parties acting in good faith but shall be [\*\*\*] in the Commercial Phase."
- c. <u>Amend Appendix A Supply Terms and Conditions</u>: The following provisions of the Supply Terms and Conditions (Appendix A) are hereby deleted and restated as follows:
  - i. <u>1A.2</u>: "At any time after the Amendment No. 1 Effective Date, Customer may notify Life that it wishes to enter into the Commercial Phase. The Commercial

- Phase Notification will specify when Customer wishes the Commercial Phase to start and its forecasted orders for Products"
- ii. <u>1.1</u>: Clause 1.1 shall be deleted in its entirety and there shall be no requirement for Customer to exclusively purchase Customer's needs for all CD3/CD28 magnetic bead products from Life.
- iii. 1.3: Clause 1.3 will be deleted and replaced with the following: "Products will be supplied under the Limited Use Label Licenses at Exhibit E-1, E-2 and E-3. The applicable LULL shall be determined by the SKU for the relevant Product and the current Phase save that the LULL at E-3 will apply to any manufacture and supply of Customer's cell therapy using Products from the Initial Order for treatment of sarcoma irrespective of the Phase."
- iv. <u>2.1</u>: "Binding Purchase Order: Customer shall provide Life with a binding purchase order for the binding element of each rolling forecast for the amount of Products specified by Customer. For clarity, purchase orders may only be placed for Products under [\*\*\*] during the [\*\*\*] and [\*\*\*] and may only be placed for Products under [\*\*\*]. Except for the Development Phase Purchasing Obligation, as part of any other purchase order during the Development Phase, Customer may specify [\*\*\*] in relation to such order provided such [\*\*\*] does not extend over a period of more than [\*\*\*] from first delivery under such purchase order."
- v. <u>2.2</u>: "Rolling forecast: On or before July 1 of each calendar year of this Agreement, Customer shall submit a [\*\*\*] written forecast to Life, which shall specify the estimated number of vials of Products required by Customer. The [\*\*\*] of such forecast will be binding on Customer. For the purposes of this Amendment, this forecasting mechanism shall commence on [\*\*\*] with binding element applicable [\*\*\*] and be in effect for the Term of the Supply Agreement."
- vi. <u>9.2</u>: "Life shall have the right to adjust the price for the Products [\*\*\*] (first commencing [\*\*\*]; provided, however, that increases in the price from [\*\*\*]. Life shall confirm the Price of Products applicable from commencement of the Commercial Phase during the Transitional Phase and as soon as reasonably possible after start of Transitional Phase. In confirming such Price, Life shall act reasonably and shall not [\*\*\*]"
- d. Amend definition of Batch. The definition of "Batch" in Appendix B is hereby deleted.
- e. <u>Amend definition of Current Manufacturing Process</u>. The definition of "Current Manufacturing Process" in Appendix B is hereby deleted and replaced in its entirety by the following: ""**Current Manufacturing Process"** means the Product manufacturing process in place as at the Effective Date."
- **f.** Amend Appendix D. Appendix D of the Supply Agreement is amended as follows:

SKU	<b>F</b>		Single Order	Price
		Commitment	Quantity	
Developmen	t Phase and Transitiona	l Phase supply (unless otherwise agree	ed)	

43300D	Dynabeads∏ CD3/CD28	[***]	[***]	[***]
	CTS™ (Clinical Research)			

- 2. The following amendments shall be made to the License Agreements.
  - a. <u>Change from Exclusive to Non-exclusive under the LTC-ADAPTIMMUNE License Agreement:</u> As of the Amendment No. 1 Effective Date, clause 2.1(a) and clause 2.1(b) and shall be amended such that any reference to an exclusive license is replaced with a non-exclusive license.
  - b. <u>Change to Sublicense Agreement</u>. As of the Amendment No. 1 Effective Date clause 2.1(a) shall be amended such that any reference to an exclusive license is replaced with a non-exclusive license.
  - c. For the avoidance of doubt amendments under this Section include the terms of any and all Limited Use Label Licenses ("LULL(s)"), including but not limited to those LULL's listed in Appendix E of the Supply Agreement.
  - d. <u>Change to remove obligations and restrictions related to exclusivity under the LTC-ADAPTIMMUNE License Agreement</u>: Any and all obligations and/or restrictions on LTC related to the LTC Bead and LTC Engineered T Cell Receptor products and imposing a requirement for exclusivity or exclusivity of supply on LTC, including, but not limited to, Sections 3.11 and 3.12 of the LTC-ADAPTIMMUNE License Agreement, are hereby deleted in their entirety.
  - e. <u>Change to remove obligations and restrictions on LTC relating to exclusivity under the Sublicense Agreement</u>: Any and all obligations and/or restrictions on LTC related to the LTC Bead and LTC Engineered T Cell Receptor products and imposing a requirement for exclusivity or exclusivity of supply on LTC, including, but not limited to Sections 3.10 and 3.11 of the Sublicense Agreement, are hereby deleted in their entirety.
- 3. Capitalized words used but not defined in this Amendment No. 1 shall have the meaning ascribed to them in the Supply Agreement.
- 4. This Amendment shall be governed by, and construed in accordance with, the laws which govern the Supply Agreement, and the Parties submit to the jurisdiction and dispute resolution provisions as set forth in the Supply Agreement.
- 5. Except as amended and supplemented herein, all terms and provisions of the Supply Agreement shall remain unchanged and in full force and effect. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment. No alteration or amendment to this Amendment No. 1 shall be binding on any Party hereto unless reduced to writing and signed by both Parties.
- 6. This Amendment No. 1 may be executed (including via facsimile signatures) by the Parties in counterparts, each of which when so executed and delivered shall be deemed to be an original, but all of which shall constitute one and the same agreement, binding on the Parties as if each had signed the same document.

IN WITNESS WHEREOF, the Parties hereto have hereby duly executed this Amendment No. 1 as of the date of last signature below. This Amendment No. 1 shall be effective as of the Amendment No. 1 Effective Date.

ADAPTIMMUNE Limited

Officer
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**Life Technologies Corporation** 

### **Consent of Independent Registered Public Accounting Firm**

The Board of Directors
Adaptimmune Therapeutics plc:

We consent to the incorporation by reference in the registration statement (No. 333-212713) on Form S-3 of Adaptimmune Therapeutics plc of our reports dated February 27, 2020, with respect to the consolidated balance sheets of Adaptimmune Therapeutics plc as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in equity, and cash flows for each of the years in the two year period ended December 31, 2019, and the related notes (collectively, the "consolidated financial statements"), and the effectiveness of internal control over reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of Adaptimmune Therapeutics plc .

Our report dated February 27, 2020 on the 2019 consolidated financial statements refers to a change in the method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standard Codification Topic 842, *Leases*, and a change to the method of accounting for revenue from contracts with customers as of January 1, 2018 due to the adoption of the Accounting Standard Codification Topic 606, *Revenue from Contracts with Customers*.

/s/ KPMG LLP

Reading, United Kingdom February 27, 2020

# 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;
    - 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):
    - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020
/s/ Adrian Rawcliffe
Adrian Rawcliffe
Chief Executive Officer and Director

# 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, Michael Garone, 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;
  - 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020 /s/ Michael Garone Michael Garone

Interim Chief Financial Officer

### **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, 2019, 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: February 27, 2020

/s/ Adrian Rawcliffe
Adrian Rawcliffe
Chief Executive Officer and Director

### **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, Michael Garone, Interim 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, 2019, 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: February 27, 2020

/s/ Michael Garone
Michael Garone

Interim Chief Financial Officer